

US3412127 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:36:14

All time stamps listed in this document are displayed in GMT

US3412127

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:22:29

Generated On: 09 Jun 2021 17:36:14

[Participant ID](#)

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

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Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

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

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:49:42

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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 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:49:42

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Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:49:42

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 04:49:42

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Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

Condition	ANXIETY
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

Condition	DEPRESSION
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

Condition	PTSD
Start date (dd MMM yyyy)	UN UNK 2012
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2012
Start Year (derived)	2012
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

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

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
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
Height (xxx.x)	170 cm
Weight (xxx.x)	72.5 kg
BMI (xxx.x)	25.08651 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 04:49:42

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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

Data signed: (b) (4) 13 Feb 2021 04:49:42

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Occupational Risk

Healthcare workers (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers) Yes ☒ No ☐

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers) Yes ☐ No ☒

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores) Yes ☐ No ☒

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants) Yes ☐ No ☒

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities) Yes ☐ No ☒

Transportation and delivery services (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers) Yes ☐ No ☒

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing) Yes ☐ No ☒

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services) Yes ☐ No ☒

Hospitality and Tourism Workers (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts) Yes ☐ No ☒

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy) Yes ☐ No ☒

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting) Yes ☐ No ☒

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:49:42

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	05 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Was study treatment given? Yes ☒ No ☐

If No, reason not given

Participant declined due to Adverse Event ☐

Physician withheld dose due to Adverse Event ☐

Death ☐

Lost To Follow-Up ☐

Physician Decision ☐

Pregnancy ☐

Protocol Deviation ☐

Study Terminated by Sponsor ☐

Withdrawal of Consent by Participant ☐

Confirmed COVID-19 ☐

Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 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

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	5 AUG 2020
Collection time (00:00-23:59)	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

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 09:31

PC Open Date & Time

05 AUG 2020 09:15

PC Close Date & Time

05 AUG 2020 11:45

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was TEMPERATURE taken?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Please record your TEMPERATURE in °F	97.4 °F
Was any MEDICATION TAKEN today for pain or fever?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.4 °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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 09 Jun 2021 17:36:14

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 3

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 4

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

50 of 2045

EAB) (1725)

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

52 of 2045

EAB) (1725)

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

56 of 2045

EAB) (1725)

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:49:41

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 13 Feb 2021 04:49:41

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

27 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412127

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:49:41

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	03 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Timepoint	Pre-Dose <input checked="" type="radio"/>
	Post-Dose <input type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	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)

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Timepoint	Pre-Dose <input type="radio"/>
	Post-Dose <input checked="" type="radio"/>
Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	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 <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
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

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Was study treatment given? Yes ☒ No ☐

If No, reason not given Participant declined due to Adverse Event ☐
Physician withheld dose due to Adverse Event ☐
Death ☐
Lost To Follow-Up ☐
Physician Decision ☐
Pregnancy ☐
Protocol Deviation ☐
Study Terminated by Sponsor ☐
Withdrawal of Consent by Participant ☐
Confirmed COVID-19 ☐
Other ☐

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

What was the study treatment? MRNA-1273 OR PLACEBO

What was the treatment date? (dd MMM yyyy) 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

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	03 SEP 2020
Collection time (00:00-23:59)	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

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

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: 09 Jun 2021 17:36:14

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 2

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☒

No ☐

Please record - **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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 3

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 5

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 7

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

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: 09 Jun 2021 17:36:14

TIMEPOINT

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

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 3

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:14

Yes <input type="checkbox"/>	
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

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 13 Feb 2021 04:49:42

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:36

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 13 Feb 2021 02:37:36

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 02:37:36

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 13 Feb 2021 02:37:36

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT3

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3412127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

US3412127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

02 OCT 2020

Collection time (00:00-23:59)

12:31 (24 HR)

Collection date and time (derived)

02 OCT 2020 12:31

US3412127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:46

Generated On: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	23 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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 NOV 2020 16:55:27

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: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 DEC 2020 18:30:40

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 138

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

18 DEC 2020 18:31:06

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 145

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

25 DEC 2020 16:38:06

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 152

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 159

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 JAN 2021 13:14:42

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 166

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 173

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 JAN 2021 05:46:58

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 JAN 2021 08:57:58

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 09:56:26

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 FEB 2021 13:42:33
Patient Cloud Open Date & Time	12 FEB 2021 00:01
Patient Cloud Close Date & Time	16 FEB 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	19 FEB 2021 09:39:48
Patient Cloud Open Date & Time	19 FEB 2021 00:01
Patient Cloud Close Date & Time	23 FEB 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 208

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 FEB 2021 07:00:30

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 MAR 2021 10:30:48

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 10:06:19

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 11:07:19

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

26 MAR 2021 13:17:01

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

02 APR 2021 15:12:33

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

11 APR 2021 07:57:25

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 257

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 APR 2021 20:07:06

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 264

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

24 APR 2021 11:17:57

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 271

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 14:42:49

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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 278

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 285

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 327

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

Have 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: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 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: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 348

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 362

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 369

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 376

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

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

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

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

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

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

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

Have 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: 09 Jun 2021 17:36:14

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

Patient Cloud Open Date & Time	13 AUG 2021 00:01
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Patient Cloud Close Date & Time	17 AUG 2021 23:59
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US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 383
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 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: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 390
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 397

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 404

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 418

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 425

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 432

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 439
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 453

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 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: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 495
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 502

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 509

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 516

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 523

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

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

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

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

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

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

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

Have 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: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 537

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 558

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

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

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

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

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

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

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

Have 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: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 565

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

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

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

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

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

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

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

Have 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: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 MAR 2022 00:01

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08 MAR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

11 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

15 MAR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 593

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

18 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

22 MAR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

29 MAR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 607

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

08 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	15 APR 2022 00:01
Patient Cloud Close Date & Time	19 APR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 APR 2022 00:01
Patient Cloud Close Date & Time	26 APR 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 656

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 663

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 677

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 684

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 698

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

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: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 705
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 712

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

26 JUL 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 754

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 761

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 775

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

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

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

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

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

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

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT

DAY 789

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

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

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

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

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

Fever (Temperature \geq 100.4°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: 09 Jun 2021 17:36:14

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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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: 09 Jun 2021 17:36:14

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

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

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:36:14

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?	Have you ever received a dermal filler, such as Juvederm, Voluma, Radiesse, Restylane, or Botox or other for a medical indication such as a migraine headache?	Date & Time of Submission
No		05 MAR 2021 10:30:41

US3412127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:32:04

Generated On: 09 Jun 2021 17:36:14

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

Data signed: (b) (4) 10 Mar 2021 19:32:04

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 4 DEC 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 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 31 DEC 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 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 2 FEB 2021

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 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:22:31

Generated On: 09 Jun 2021 17:36:14

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

Visit date (dd MMM yyyy)	05 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:22:31

Generated On: 09 Jun 2021 17:36:14

Were vital signs assessed? Yes ☐
No ☒

Date of assessment (dd MMM yyyy) _____

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

Vital Signs Date and Time (derived) _____

Temperature (xxx.x) _____

Route of measurement Oral ☐
Axillary ☐
Other ☐

If Other, specify _____

Pulse (xxx) _____

Pulse units _____

Respiratory Rate (xxx) _____

Respiratory Rate units _____

Systolic Blood Pressure (xxx) _____

Systolic Blood Pressure units _____

Diastolic Blood Pressure (xxx) _____

Diastolic Blood Pressure units _____

Height (derived) _____

Weight (derived) _____

US3412127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:22:31

Generated On: 09 Jun 2021 17:36:14

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

05 MAR 2021

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

US3412127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:22:31

Generated On: 09 Jun 2021 17:36:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	05 MAR 2021
Collection time (00:00-23:59)	11:38 (24 HR)
Collection date and time (derived)	05 MAR 2021 11:38

US3412127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:31

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:31

Generated On: 09 Jun 2021 17:36:14

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 1 APR 2021

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 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:31

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412127

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

Was Contact Attempted? Yes ☐
No ☐

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

Please select one status for the follow-up contact

Contact Made ☐

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412127

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412127

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:36:14

Date of Contact	
Time of Contact	
Date and Time of Contact (derived)	
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input type="checkbox"/>
	No <input type="checkbox"/>

US3412127

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:36:14

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412127

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:22:29

Generated On: 09 Jun 2021 17:36:14

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

Visit date (dd MMM yyyy)	15 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3412127

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:22:29

Generated On: 09 Jun 2021 17:36:14

Date of updated informed consent (dd MMM yyyy) 15 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study

Was the participant unblinded? Yes ☐
No ☒

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐
Amendment 6 or later ☐

Date of unblinding (dd MMM yyyy)

Participant randomization assignment mRNA-1273 ☐
Placebo ☐

Actual Dose 1 mRNA-1273 ☐
Placebo ☐
Not Administered ☐

Actual Dose 2 mRNA-1273 ☐
Placebo ☐
Not Administered ☐

Will participant receive mRNA-1273? Yes ☐
No ☐

Placebo Only Flag

Continuing with mRNA-1273

US3412127

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:22:29

Generated On: 09 Jun 2021 17:36:14

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

Collection date (dd MMM yyyy)	15 JAN 2021
-------------------------------	-------------

Collection time (00:00-23:59)	07:55 (24 HR)
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Collection date and time (derived)	15 JAN 2021 07:55
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US3412127

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:22:29

Generated On: 09 Jun 2021 17:36:14

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	15 JAN 2021
Collection time (00:00 - 23:59)	08:02
Collection Date and Time (derived)	15 JAN 2021 08:02

US3412127

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:31:05

Generated On: 09 Jun 2021 17:36:14

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)

Data signed: (b) (4) 15 Mar 2021 15:31:04

Generated On: 09 Jun 2021 17:36:14

AEID	USA-US061-2020-MRNA-1273-P30 1000001
Adverse event	ACUTE RESPIRATORY FAILURE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	14 AUG 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	20 AUG 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	16 AUG 2020
Hospital Discharge Date (dd MMM yyyy)	20 AUG 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:31:04

Generated On: 09 Jun 2021 17:36:14

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

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 15 Mar 2021 15:31:04

Generated On: 09 Jun 2021 17:36:14

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	0

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:35:06

Generated On: 09 Jun 2021 17:36:14

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)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 AUG 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	19 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="radio"/>	
	803 <input type="radio"/>	
	804 <input checked="" type="radio"/>	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	24 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

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 ☐

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EAB) (1725)

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	19 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	4	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		17 AUG 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		19 AUG 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

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 ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	17 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	19 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

Name of Medication SYMBICORT (160 / 4.5 MCG)

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 ☐

PRODUCTION RELEASE (v12.003

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	12 DEC 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="checkbox"/>	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication ACUTE RESPIRATORY FAILURE

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input checked="" type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

Name of Medication LEVAQUIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE RESPIRATORY FAILURE

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 12 Apr 2021 14:17:03

Generated On: 09 Jun 2021 17:36:14

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	16 AUG 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	23 AUG 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input checked="" type="radio"/>	

US3412127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:35:06

Generated On: 09 Jun 2021 17:36:14

Were any concomitant procedures performed?

Yes ☐

No ☒

If yes, please complete Concomitant Procedures form.

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Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:36:14

Date of dosing discontinuation (dd MMM yyyy)

Primary reason for dosing discontinuation

AE (specify) ☐

SAE (specify) ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Due to SARS-COV-2 ☐

Other ☐

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

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Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:36:14

Date of study discontinuation/completion (*dd MMM yyyy*)

Reason for discontinuation

AE (specify) ☐

SAE (specify) ☐

Complete ☐

Death ☐

Lost To Follow-up ☐

Physician decision (specify) ☐

Pregnancy ☐

Protocol deviation (specify) ☐

Study Terminated By Sponsor ☐

Withdrawal of consent by
participant (specify) ☐

Other ☐

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

If reason for discontinuation is Death, main cause of death

Adverse event ☐

Unknown ☐

Other ☐

If main cause of death is Other, specify

Date of death (*dd MMM yyyy*)

Was autopsy performed?

Yes ☐

No ☐

Unknown ☐

US3412127

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

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

SAEID	USA-US061-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6

US3412127

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

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

SAEID	USA-US061-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
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)

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

SAEID	USA-US061-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
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)

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

SAEID	USA-US061-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
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)

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

SAEID	USA-US061-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
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)

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

SAEID	USA-US061-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
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

US3412127

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

Form: Safety Report Form (6)

Data signed: (b) (4) 16 Apr 2021 14:22:30

Generated On: 09 Jun 2021 17:36:14

SAEID	USA-US061-2020-MRNA-1273-P301000001
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	6
Date of submission (Pre-filled from custom function)	05/JAN/2021 12:29
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

Audit

US3412127 (Prod: New Horizons Clinical Research)

US3412127

Form: Participant Creation

Generated On: 09 Jun 2021 17:36:14

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'US3412127'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 11:49:19

US3412127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:38:33

US3412127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 11:49:20

US3412127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:38:33

US3412127

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'SCRN'	System	05 Aug 2020 12:38:33

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered (b) (6) 1978'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 11:49:21

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '42'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'YEARS'	System	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered '42'	System	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User closed query 'Race has not been provided. Please correct.' (Site from System).	(b) (4)	05 Aug 2020 12:40:21
User entered '1' reason for change: Data Entry Error	System	05 Aug 2020 12:40:21
User opened query 'Race has not been provided. Please correct.' (Site from System).	(b) (4), (b) (6)	05 Aug 2020 12:40:06
User entered '0'	System	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:36:14

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:40:06

US3412127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:14

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '05 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'Aug 2020'	System	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered '2020'	System	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:14

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:14

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:14

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:41:08

US3412127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:14

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 11:49:20

US3412127

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:36:14

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'I'	System	05 Aug 2020 12:41:18

US3412127

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:41:18

US3412127

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:36:14

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:19:14

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:14

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4)	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 17:20:12
User entered 'HYPERLIPIDEMIA'	(b) (4), (b) (6)	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
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).	(b) (4)	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: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0' reason for change: Data Entry Error	(b) (4), (b) (6)	18 Aug 2020 21:40:31
User entered '1'		14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'Jan 2012'	System	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered '2012'	System	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	14 Aug 2020 17:19:37

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User coded data point as SOC: Psychiatric disorders, HLT: 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: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'Jan 2012'	System	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered '2012'	System	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	14 Aug 2020 17:20:01

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User coded data point as SOC: Psychiatric disorders, HLG: 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: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'Jan 2012'	System	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered '2012'	System	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	14 Aug 2020 17:20:15

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User coded data point as SOC: Psychiatric disorders, HLT: 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)	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)	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: 09 Jun 2021 17:36:14

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'UN UNK 2012'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'Jan 2012'	System	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered '2012'	System	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:36:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	14 Aug 2020 17:20:31

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:14

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
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)	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)	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: 09 Jun 2021 17:36:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
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: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:14

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:14

[If No, please specify the stop date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:14

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:14

[Start Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'Jan 2018'	System	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:14

[Start Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered '2018'	System	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:14

[Stop Month and Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:36:14

[Stop Year \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	22 Oct 2020 21:50:07

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '5 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '07:56'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered '5 Aug 2020 07:56'	System	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '170' cm	(b) (4) (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: 09 Jun 2021 17:36:14

[Weight \(xxx.x\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '72.5' kg	(b) (4) (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: 09 Jun 2021 17:36:14

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
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: 09 Jun 2021 17:36:14

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
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: 09 Jun 2021 17:36:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
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).		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: 09 Jun 2021 17:36:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'bpm'	System	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'breaths/min'	System	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'mmHg'	System	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Diastolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'mmHg'	System	14 Aug 2020 17:25:13

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02

US3412127

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02

US3412127

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:25:44

US3412127

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (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).	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: 09 Jun 2021 17:36:14

[Healthcare workers](#) (e.g., doctors, nurses, dentists, hospital support staff, morgue/mortuary workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

Emergency Response (e.g., Law enforcement officers, Firefighters, emergency medical service workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

[Warehouse shipping and fulfillment centers and jobs \(e.g., Amazon facilities\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

[Resides in high density housing](#) (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'I'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '0'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:36:14

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:26:16

US3412127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:41:56

US3412127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '05 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:41:56

US3412127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:41:56

US3412127

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'VISIT1'	System	05 Aug 2020 12:41:56

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:14

What was the date of randomization? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '05 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:34:10

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:14

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	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)	05 Aug 2020 12:34:10

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:14

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '>=18 and <65 years and not at risk (1)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	05 Aug 2020 12:34:10

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:14

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:27:01

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:14

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:27:01

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:14

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:27:01

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:14

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:27:01

US3412127

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:36:14

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:27:01

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:14

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User accepted default value 'Pre-Dose (PREDOSE)'		14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '5 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '07:56'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '96.8' F	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '80'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'bpm'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '16'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'breaths/min'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '116'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'mmHg'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '86'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'mmHg'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:14

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:36:14

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User accepted default value 'Post-Dose (POSTDOSE)'		14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '5 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
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)	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: 09 Jun 2021 17:36:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '98.1' F	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '62'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'bpm'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '14'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'breaths/min'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '120'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'mmHg'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '80'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'mmHg'	System	14 Aug 2020 17:29:27

US3412127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:42

US3412127

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:14

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:29:42

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'MRNA-1273 OR PLACEBO'	System	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '05 Aug 2020'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '08:55'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered '05 Aug 2020 08:55'	System	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'ONCE'	System	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'INTRAMUSCULAR'	System	05 Aug 2020 12:59:26

US3412127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:30:30

US3412127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '5 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:30:30

US3412127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '08:22'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:30:30

US3412127

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '5 Aug 2020'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:14

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '08:24'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:14

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:36:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered empty.	System	14 Aug 2020 17:30:54

US3412127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:31:16

US3412127

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'I'	System	14 Aug 2020 17:31:16

US3412127

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

To **TREAT** pain or fever that has already occurred

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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).		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).		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).		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).		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).		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: 09 Jun 2021 17:36:14

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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'	System	06 Aug 2020 22:04:34
User entered '06 Aug 2020 18:04'	System	06 Aug 2020 22:04:34

US3412127

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	22 Sep 2020 16:16:24

US3412127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '12 Aug 2020'	Jacob sekinger (b) (4)	22 Sep 2020 16:16:24

US3412127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Contact Made (CONTACT MADE)'	Jacob sekinger (b) (4)	22 Sep 2020 16:16:24

US3412127

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	Jacob sekinger (b) (4)	22 Sep 2020 16:16:24

US3412127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:19:11

US3412127

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User entered 'I'	System	03 Sep 2020 22:19:11

US3412127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Sep 2020 19:01:23

US3412127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
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: 09 Jun 2021 17:36:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	17 Sep 2020 19:01:23

US3412127

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	Mason Urban (b) (4)	17 Sep 2020 19:01:23

US3412127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:19:21

US3412127

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User entered 'I'	System	03 Sep 2020 22:19:21

US3412127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	22 Sep 2020 16:17:25

US3412127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '27 Aug 2020'	Jacob sekinger (b) (4)	22 Sep 2020 16:17:25

US3412127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Contact Made (CONTACT MADE)'	Jacob sekinger (b) (4)	22 Sep 2020 16:17:25

US3412127

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	Jacob sekinger (b) (4)	22 Sep 2020 16:17:25

US3412127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:19:37

US3412127

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User entered 'I'	System	03 Sep 2020 22:19:37

US3412127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:20:09

US3412127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:20:09

US3412127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:20:09

US3412127

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'VISIT2'	System	03 Sep 2020 22:20:09

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '03 Sep 2020'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '17:25'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '37.1' C	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '70'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'bpm'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '14'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

[Systolic Blood Pressure \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '116'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'mmHg'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '70'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:36:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'mmHg'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '03 Sep 2020'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '18:48'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '97.8' F	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '58'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'bpm'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '12'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '124'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'mmHg'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '80'	Jacob sekinger (b) (4)	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:36:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'mmHg'	System	22 Sep 2020 16:22:35

US3412127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	22 Sep 2020 16:23:07

US3412127

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '03 Sep 2020'	Jacob sekinger (b) (4)	22 Sep 2020 16:23:07

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

If reason is Physician Decision, Withdrawal of Consent by Participant, Protocol Deviation, or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'MRNA-1273 OR PLACEBO'	System	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '03 Sep 2020'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '18:17'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'ONCE'	System	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:36:14

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'INTRAMUSCULAR'	System	03 Sep 2020 22:21:17

US3412127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	22 Sep 2020 16:24:22

US3412127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '03 Sep 2020'	Jacob sekinger (b) (4)	22 Sep 2020 16:24:22

US3412127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '17:40'	Jacob sekinger (b) (4)	22 Sep 2020 16:24:22

US3412127

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '03 Sep 2020'	Jacob sekinger (b) (4)	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4)	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '17:43'	Jacob sekinger (b) (4)	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:36:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'No (N)'	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: 09 Jun 2021 17:36:14

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	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: 09 Jun 2021 17:36:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered empty.	System	22 Sep 2020 16:24:52

US3412127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:29:36

US3412127

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'I'	System	10 Sep 2020 20:29:36

US3412127

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Was any **MEDICATION TAKEN** today for pain or fever?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **SWELLING/HARDNESS AT INJECTION SITE (in mm)**

Measure the largest size across any injection site swelling/hardness with the ruler provided.

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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-8da4-0fbeeeldc922'	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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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-8da4-0fbee1dc922'	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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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-8da4-0fbee1dc922'	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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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-8da4-0fbeeelcdc922'	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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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-8da4-0fbeeelcdc922'	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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **PAIN AT INJECTION SITE.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **REDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Is there any **SWELLING/HARDNESS AT INJECTION SITE?**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Please record - **UNDERARM GLAND SWELLING OR TENDERNESS.**

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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' User entered 'None (0)'	System	09 Sep 2020 21:57:47
	System	09 Sep 2020 21:57:47

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:14

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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' User entered 'None (0)'	System	09 Sep 2020 21:57:47
	System	09 Sep 2020 21:57:47

US3412127

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:36:14

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Did you receive any **MEDICAL ATTENTION** (doctor visit, other) for any illness or symptoms?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:29:51

US3412127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered '10 Sep 2020'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:29:51

US3412127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:29:51

US3412127

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:29:51

US3412127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:42
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Sep 2020 20:29:58

US3412127

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User entered 'I'	System	10 Sep 2020 20:29:58

US3412127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:36
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Sep 2020 19:02:12

US3412127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:36
User entered '17 Sep 2020'	Mason Urban (b) (4)	17 Sep 2020 19:02:12

US3412127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:36
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	17 Sep 2020 19:02:12

US3412127

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:36
User entered empty.	Mason Urban (b) (4)	17 Sep 2020 19:02:12

US3412127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:36
User entered 'Yes (Y)'	Mason Urban (b) (4)	17 Sep 2020 19:02:16

US3412127

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User entered 'I'	System	17 Sep 2020 19:02:16

US3412127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:36
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Sep 2020 18:13:56

US3412127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:36
User entered '25 Sep 2020'	Mason Urban (b) (4)	25 Sep 2020 18:13:56

US3412127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:36
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	25 Sep 2020 18:13:56

US3412127

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:36
User entered empty.	Mason Urban (b) (4)	25 Sep 2020 18:13:56

US3412127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:36
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Sep 2020 18:15:26

US3412127

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User entered 'I'	System	25 Sep 2020 18:15:26

US3412127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:02:19

US3412127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '02 Oct 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:02:19

US3412127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	02 Oct 2020 17:02:19

US3412127

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'VISIT3'	System	02 Oct 2020 17:02:19

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered empty.	System	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered empty.	System	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered empty.	System	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered empty.	System	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered empty.	System	02 Oct 2020 17:02:27

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52

US3412127

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52

US3412127

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
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: 09 Jun 2021 17:36:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
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: 09 Jun 2021 17:36:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:05:07

US3412127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '02 Oct 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:05:07

US3412127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered '12:31'	Steven Anderson (b) (4)	02 Oct 2020 17:05:07

US3412127

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
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: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:47
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:05:15

US3412127

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:52
User entered 'I'	System	02 Oct 2020 17:05:15

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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'	System	23 Oct 2020 10:22:56
User entered '23 Oct 2020 06:22:43'	System	23 Oct 2020 10:22:56

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: 09 Jun 2021 17:36:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:13:56
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: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51
Data entry locked.	System	05 Aug 2020 12:59:26
User entered 'Day 106'	System	05 Aug 2020 12:59:26

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51

US3412127

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '16 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: 09 Jun 2021 17:36:14

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 13:06:51
Data entry locked.	System	05 Aug 2020 12:59:26
User entered '20 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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[Have you been exposed to someone with 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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2020-11-27T16:55:17', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2643ea0a-e09d-49b4-a1ee-fb2f79ac596c'	System	27 Nov 2020 21:55:28
User entered 'No (N)'	System	27 Nov 2020 21:55:28

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2020-11-27T16:55:24', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2643ea0a-e09d-49b4-a1ee-fb2f79ac596c'	System	27 Nov 2020 21:55:28
User entered 'No (N)'	System	27 Nov 2020 21:55:28

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-11-27T16:55:27', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2643ea0a-e09d-49b4-a1ee-fb2f79ac596c' User entered '27 Nov 2020 16:55:27'	System	27 Nov 2020 21:55:28
	System	27 Nov 2020 21:55:28

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2020-12-11T18:30:34', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '60bb58e9-0c88-4dae-aa23-d6570d3c8649'	System	11 Dec 2020 23:30:44
User entered 'No (N)'	System	11 Dec 2020 23:30:44

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2020-12-11T18:30:38', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '60bb58e9-0c88-4dae-aa23-d6570d3c8649'	System	11 Dec 2020 23:30:44
User entered 'No (N)'	System	11 Dec 2020 23:30:44

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-12-11T18:30:40', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '60bb58e9-0c88-4dae-aa23-d6570d3c8649'	System	11 Dec 2020 23:30:44
User entered '11 Dec 2020 18:30:40'	System	11 Dec 2020 23:30:44

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2020-12-18T18:30:54', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2d5dbfe1-333b-482b-b60d-a17a86b63649'	System	18 Dec 2020 23:31:15
User entered 'No (N)'	System	18 Dec 2020 23:31:15

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2020-12-18T18:31:03', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2d5dbfe1-333b-482b-b60d-a17a86b63649'	System	18 Dec 2020 23:31:15
User entered 'No (N)'	System	18 Dec 2020 23:31:15

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-12-18T18:31:06', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '2d5dbfe1-333b-482b-b60d-a17a86b63649'	System	18 Dec 2020 23:31:15
User entered '18 Dec 2020 18:31:06'	System	18 Dec 2020 23:31:15

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2020-12-25T16:38:02', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '27f7e308-3281-4296-8bfd-aa70c7eb7517'	System	25 Dec 2020 21:38:09
User entered 'No (N)'	System	25 Dec 2020 21:38:09

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Have you been exposed to someone with 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: '2020-12-25T16:38:04', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '27f7e308-3281-4296-8bfd-aa70c7eb7517'	System	25 Dec 2020 21:38:09
User entered 'No (N)'	System	25 Dec 2020 21:38:09

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2020-12-25T16:38:06', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '27f7e308-3281-4296-8bfd-aa70c7eb7517'	System	25 Dec 2020 21:38:09
User entered '25 Dec 2020 16:38:06'	System	25 Dec 2020 21:38:09

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-01-08T13:14:37', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f0c696d7-0ca1-4702-95c6-ba854a1ffb92'	System	08 Jan 2021 18:14:44
User entered 'No (N)'	System	08 Jan 2021 18:14:44

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-01-08T13:14:39', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f0c696d7-0ca1-4702-95c6-ba854a1ffb92'	System	08 Jan 2021 18:14:44
User entered 'No (N)'	System	08 Jan 2021 18:14:44

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-01-08T13:14:42', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'f0c696d7-0ca1-4702-95c6-ba854a1ffb92'	System	08 Jan 2021 18:14:44
User entered '08 Jan 2021 13:14:42'	System	08 Jan 2021 18:14:44

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-01-26T05:46:53', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8a70cbc8-615f-4d26-84e8-4d92a16fe515'	System	26 Jan 2021 10:47:02
User entered 'No (N)'	System	26 Jan 2021 10:47:02

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-01-26T05:46:55', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8a70cbc8-615f-4d26-84e8-4d92a16fe515'	System	26 Jan 2021 10:47:02
User entered 'No (N)'	System	26 Jan 2021 10:47:02

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-01-26T05:46:58', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '8a70cbc8-615f-4d26-84e8-4d92a16fe515'	System	26 Jan 2021 10:47:02
User entered '26 Jan 2021 05:46:58'	System	26 Jan 2021 10:47:02

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-01-30T08:57:53', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'ce6a2137-7932-44f0-80e7-6227de59ac5d'	System	30 Jan 2021 13:58:01
User entered 'No (N)'	System	30 Jan 2021 13:58:01

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-01-30T08:57:56', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'ce6a2137-7932-44f0-80e7-6227de59ac5d'	System	30 Jan 2021 13:58:01
User entered 'No (N)'	System	30 Jan 2021 13:58:01

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-01-30T08:57:58', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'ce6a2137-7932-44f0-80e7-6227de59ac5d' User entered '30 Jan 2021 08:57:58'	System	30 Jan 2021 13:58:01

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-02-05T09:56:22', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '84268464-b369-4a10-9b6e-a0024307c08c'	System	05 Feb 2021 14:56:43
User entered 'No (N)'	System	05 Feb 2021 14:56:43

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-02-05T09:56:23', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '84268464-b369-4a10-9b6e-a0024307c08c'	System	05 Feb 2021 14:56:43
User entered 'No (N)'	System	05 Feb 2021 14:56:43

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-02-05T09:56:26', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '84268464-b369-4a10-9b6e-a0024307c08c'	System	05 Feb 2021 14:56:43
User entered '05 Feb 2021 09:56:26'	System	05 Feb 2021 14:56:43

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-02-12T13:42:29', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd2acea34-163a-4f00-b7ae-941f0cd2948f'	System	12 Feb 2021 18:42:37
User entered 'No (N)'	System	12 Feb 2021 18:42:37

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Have you been exposed to someone with 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: '2021-02-12T13:42:31', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd2acea34-163a-4f00-b7ae-941f0cd2948f'	System	12 Feb 2021 18:42:37
User entered 'No (N)'	System	12 Feb 2021 18:42:37

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-02-12T13:42:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'd2acea34-163a-4f00-b7ae-941f0cd2948f' User entered '12 Feb 2021 13:42:33'	System	12 Feb 2021 18:42:37
	System	12 Feb 2021 18:42:37

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-02-19T09:39:45', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3a887e0b-8ad8-4808-ab81-78c827d0e5e9'	System	19 Feb 2021 14:39:50
User entered 'No (N)'	System	19 Feb 2021 14:39:50

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-02-19T09:39:46', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3a887e0b-8ad8-4808-ab81-78c827d0e5e9'	System	19 Feb 2021 14:39:50
User entered 'No (N)'	System	19 Feb 2021 14:39:50

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-02-19T09:39:48', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '3a887e0b-8ad8-4808-ab81-78c827d0e5e9'	System	19 Feb 2021 14:39:50
User entered '19 Feb 2021 09:39:48'	System	19 Feb 2021 14:39:50

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-02-26T07:00:27', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '44eb3335-fa03-457e-91cc-a07ae7d157c2'	System	26 Feb 2021 12:00:33
User entered 'No (N)'	System	26 Feb 2021 12:00:33

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-02-26T07:00:28', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '44eb3335-fa03-457e-91cc-a07ae7d157c2'	System	26 Feb 2021 12:00:33
User entered 'No (N)'	System	26 Feb 2021 12:00:33

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-02-26T07:00:30', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '44eb3335-fa03-457e-91cc-a07ae7d157c2'	System	26 Feb 2021 12:00:33
User entered '26 Feb 2021 07:00:30'	System	26 Feb 2021 12:00:33

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-03-05T10:30:45', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'db89a6e2-fcc3-48d9-8a87-7262266bd838'	System	05 Mar 2021 15:30:51
User entered 'No (N)'	System	05 Mar 2021 15:30:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Have you been exposed to someone with 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: '2021-03-05T10:30:46', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'db89a6e2-fcc3-48d9-8a87-7262266bd838'	System	05 Mar 2021 15:30:51
User entered 'No (N)'	System	05 Mar 2021 15:30:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-03-05T10:30:48', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'db89a6e2-fcc3-48d9-8a87-7262266bd838'	System	05 Mar 2021 15:30:51
User entered '05 Mar 2021 10:30:48'	System	05 Mar 2021 15:30:51

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-03-12T10:06:15', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'a41fc23a-494e-4efe-a791-66d6bf513d41'	System	12 Mar 2021 15:06:22
User entered 'No (N)'	System	12 Mar 2021 15:06:22

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-03-12T10:06:17', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'a41fc23a-494e-4efe-a791-66d6bf513d41'	System	12 Mar 2021 15:06:22
User entered 'No (N)'	System	12 Mar 2021 15:06:22

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-03-12T10:06:19', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'a41fc23a-494e-4efe-a791-66d6bf513d41'	System	12 Mar 2021 15:06:22
User entered '12 Mar 2021 10:06:19'	System	12 Mar 2021 15:06:22

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-03-19T11:06:57', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '4f297825-2cbe-4c4d-9ff0-44eae8689b91'	System	19 Mar 2021 15:07:23
User entered 'No (N)'	System	19 Mar 2021 15:07:23

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-03-19T11:06:59', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '4f297825-2cbe-4c4d-9ff0-44eae8689b91'	System	19 Mar 2021 15:07:23
User entered 'No (N)'	System	19 Mar 2021 15:07:23

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-03-19T11:07:19', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '4f297825-2cbe-4c4d-9ff0-44eae8689b91'	System	19 Mar 2021 15:07:23
User entered '19 Mar 2021 11:07:19'	System	19 Mar 2021 15:07:23

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-03-26T13:16:58', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'ebb3927a-cd6b-42de-b207-9c0f9a212dfb'	System	26 Mar 2021 17:17:07
User entered 'No (N)'	System	26 Mar 2021 17:17:07

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Have you been exposed to someone with 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: '2021-03-26T13:16:59', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'ebb3927a-cd6b-42de-b207-9c0f9a212dfb'	System	26 Mar 2021 17:17:07
User entered 'No (N)'	System	26 Mar 2021 17:17:07

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-03-26T13:17:01', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'ebb3927a-cd6b-42de-b207-9c0f9a212dfb'	System	26 Mar 2021 17:17:07
User entered '26 Mar 2021 13:17:01'	System	26 Mar 2021 17:17:07

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-04-02T15:12:29', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'b73d7a0d-16b5-49fc-bcc8-e438a8496e6f'	System	02 Apr 2021 19:12:39
User entered 'No (N)'	System	02 Apr 2021 19:12:39

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-04-02T15:12:31', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'b73d7a0d-16b5-49fc-bcc8-e438a8496e6f'	System	02 Apr 2021 19:12:39
User entered 'No (N)'	System	02 Apr 2021 19:12:39

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-04-02T15:12:33', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'b73d7a0d-16b5-49fc-bcc8-e438a8496e6f'	System	02 Apr 2021 19:12:39
User entered '02 Apr 2021 15:12:33'	System	02 Apr 2021 19:12:39

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-04-11T07:57:21', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'c221b368-e354-4c6c-b728-913819c4440f'	System	11 Apr 2021 11:57:27
User entered 'No (N)'	System	11 Apr 2021 11:57:27

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Have you been exposed to someone with 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: '2021-04-11T07:57:23', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'c221b368-e354-4c6c-b728-913819c4440f'	System	11 Apr 2021 11:57:27
User entered 'No (N)'	System	11 Apr 2021 11:57:27

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-04-11T07:57:25', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'c221b368-e354-4c6c-b728-913819c4440f' User entered '11 Apr 2021 07:57:25'	System	11 Apr 2021 11:57:27
	System	11 Apr 2021 11:57:27

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-04-19T20:07:02', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '74874180-4497-4cb5-a468-f4cbd8b322bf'	System	20 Apr 2021 00:07:09
User entered 'No (N)'	System	20 Apr 2021 00:07:09

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-04-19T20:07:03', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '74874180-4497-4cb5-a468-f4cbd8b322bf'	System	20 Apr 2021 00:07:09
User entered 'No (N)'	System	20 Apr 2021 00:07:09

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-04-19T20:07:06', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '74874180-4497-4cb5-a468-f4cbd8b322bf'	System	20 Apr 2021 00:07:09
User entered '19 Apr 2021 20:07:06'	System	20 Apr 2021 00:07:09

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-04-24T11:16:48', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '420190cb-d7a8-45ec-99f9-53f49ebcd3b5'	System	24 Apr 2021 15:17:59
User entered 'No (N)'	System	24 Apr 2021 15:17:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-04-24T11:16:49', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '420190cb-d7a8-45ec-99f9-53f49ebcd3b5'	System	24 Apr 2021 15:17:59
User entered 'No (N)'	System	24 Apr 2021 15:17:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-04-24T11:17:57', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '420190cb-d7a8-45ec-99f9-53f49ebcd3b5'	System	24 Apr 2021 15:17:59
User entered '24 Apr 2021 11:17:57'	System	24 Apr 2021 15:17:59

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: '2021-04-30T14:42:46', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'a9bc29a9-0468-436f-aae2-671788d2a01e'	System	30 Apr 2021 18:42:55
User entered 'No (N)'	System	30 Apr 2021 18:42:55

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

Have you been exposed to someone with 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: '2021-04-30T14:42:48', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'a9bc29a9-0468-436f-aae2-671788d2a01e'	System	30 Apr 2021 18:42:55
User entered 'No (N)'	System	30 Apr 2021 18:42:55

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-04-30T14:42:49', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: 'a9bc29a9-0468-436f-aae2-671788d2a01e'	System	30 Apr 2021 18:42:55
User entered '30 Apr 2021 14:42:49'	System	30 Apr 2021 18:42:55

US3412127

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:36:14

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-03-05T10:30:37', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '40add66d-4bee-449d-aeae-19489d65334d'	System	05 Mar 2021 15:30:47
User entered 'No (N)'	System	05 Mar 2021 15:30:47

US3412127

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:36:14

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:19:38
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c45938ec87da2c96)', Time: '2021-03-05T10:30:41', User OID: 'PatientReportedOutcome (US3412127)', ODM File OID: '40add66d-4bee-449d-aeae-19489d65334d'	System	05 Mar 2021 15:30:47
User entered '05 Mar 2021 10:30:41'	System	05 Mar 2021 15:30:47

US3412127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:32:04
User entered 'Yes (Y)'	Mason Urban (b) (4)	02 Nov 2020 16:46:59

US3412127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:32:04
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) (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) (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) (b) (4)	02 Nov 2020 16:46:59

US3412127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:32:04
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	02 Nov 2020 16:46:59

US3412127

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:32:04
User entered empty.	Mason Urban (b) (4)	02 Nov 2020 16:46:59

US3412127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:32:04
User entered 'Yes (Y)'	Mason Urban (b) (4)	02 Nov 2020 16:47:07

US3412127

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 20:01:51
User entered 'I'	System	02 Nov 2020 16:47:07

US3412127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Dec 2020 15:02:45

US3412127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '4 Dec 2020'	Melissa Fuson (b) (4)	06 Dec 2020 15:02:45

US3412127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Contact Made (CONTACT MADE)'	Melissa Fuson (b) (4)	06 Dec 2020 15:02:45

US3412127

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Melissa Fuson (b) (4)	06 Dec 2020 15:02:45

US3412127

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Dec 2020 15:02:53

US3412127

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User entered 'I'	System	06 Dec 2020 15:02:53

US3412127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Mason Urban (b) (4)	31 Dec 2020 17:22:01

US3412127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '31 Dec 2020'	Mason Urban (b) (4)	31 Dec 2020 17:22:01

US3412127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	31 Dec 2020 17:22:01

US3412127

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Mason Urban (b) (4)	31 Dec 2020 17:22:01

US3412127

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Mason Urban (b) (4)	31 Dec 2020 17:22:12

US3412127

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User entered 'I'	System	31 Dec 2020 17:22:12

US3412127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Mason Urban (b) (4)	03 Feb 2021 18:26:43

US3412127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '2 Feb 2021'	Mason Urban (b) (4)	03 Feb 2021 18:26:43

US3412127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	03 Feb 2021 18:26:43

US3412127

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Mason Urban (b) (4)	03 Feb 2021 18:26:43

US3412127

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Mason Urban (b) (4)	03 Feb 2021 18:27:19

US3412127

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 02:08:28
User entered 'I'	System	03 Feb 2021 18:27:19

US3412127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Mar 2021 18:39:18

US3412127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '05 Mar 2021'	Andrea Newlands (b) (4)	08 Mar 2021 18:39:18

US3412127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	08 Mar 2021 18:39:18

US3412127

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'VISIT4'	System	08 Mar 2021 18:39:18

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'No (N)'	Andrea Newlands (b) (4)	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Time of assessment (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Vital Signs Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered empty.	System	30 Mar 2021 14:31:01

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02

US3412127

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:36:14

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02

US3412127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:14

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Mar 2021 18:39:22

US3412127

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:36:14

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '05 Mar 2021'	Andrea Newlands (b) (4)	08 Mar 2021 18:39:22

US3412127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Mar 2021 18:39:29

US3412127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '05 Mar 2021'	Andrea Newlands (b) (4)	08 Mar 2021 18:39:29

US3412127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '11:38'	Andrea Newlands (b) (4)	08 Mar 2021 18:39:29

US3412127

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered '05 Mar 2021 11:38'	System	08 Mar 2021 18:39:29

US3412127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Mar 2021 18:39:32

US3412127

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 12:17:02
User entered 'I'	System	08 Mar 2021 18:39:32

US3412127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:25:15

US3412127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '1 Apr 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:25:15

US3412127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:25:15

US3412127

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:36:14

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:25:15

US3412127

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 17:25:18

US3412127

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:36:14

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	01 Apr 2021 17:25:18

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	15 Jan 2021 19:39:57

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Visit date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '15 Jan 2021'	Melissa Fuson (b) (4)	15 Jan 2021 19:39:57

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Was visit performed at the participant's home or at the clinic?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Clinic (Clinic)'	Melissa Fuson (b) (4)	15 Jan 2021 19:39:57

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:36:14

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User entered 'UNBLND_DECIDE'	System	15 Jan 2021 19:39:57

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:36:14

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '15 Jan 2021'	Melissa Fuson (b) (4)	15 Jan 2021 19:45:24

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:36:14

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:28:28

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:36:14

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'No (N)'	Melissa Fuson (b) (4)	15 Jan 2021 19:45:24

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:36:14

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:28:28

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:36:14

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Melissa Fuson (b) (4)	15 Jan 2021 19:45:24

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:36:14

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Melissa Fuson (b) (4)	15 Jan 2021 19:45:24

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:36:14

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Melissa Fuson (b) (4)	15 Jan 2021 19:45:24

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:36:14

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Melissa Fuson (b) (4)	15 Jan 2021 19:45:24

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:36:14

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered empty.	Melissa Fuson (b) (4)	15 Jan 2021 19:45:24

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:36:14

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User entered empty.	System	15 Jan 2021 19:45:24

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Unblinding

Generated On: 09 Jun 2021 17:36:14

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User entered empty.	System	15 Jan 2021 19:45:24

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	15 Jan 2021 19:45:46

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '15 Jan 2021'	Melissa Fuson (b) (4)	15 Jan 2021 19:45:46

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '07:55'	Melissa Fuson (b) (4)	15 Jan 2021 19:45:46

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:36:14

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User entered '15 Jan 2021 07:55'	System	15 Jan 2021 19:45:46

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:14

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	15 Jan 2021 19:46:06

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:14

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '15 Jan 2021'	Melissa Fuson (b) (4)	15 Jan 2021 19:46:06

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:14

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
User entered '08:02'	Melissa Fuson (b) (4)	15 Jan 2021 19:46:06

US3412127

Folder: Participant Decision Visit / OL-D1 (1)

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:36:14

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:28
User entered '15 Jan 2021 08:02'	System	15 Jan 2021 19:46:06

US3412127

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:36:14

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:19:19
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	17 Aug 2020 19:39:47

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4)	07 Nov 2020 02:57:08
Reviewed for Safety.	(b) (4), (b) (6)	18 Aug 2020 13:04:21
User entered	System	18 Aug 2020 13:03:59
'USA-US061-2020-mRNA-1273-P301000001'		
User entered 'New'	(b) (4), (b) (6)	18 Aug 2020 13:03:59

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4)	
	(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).		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, HLG: 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		23 Sep 2020 17:10:35
User coded data point as SOC: Infections and infestations, HLG: 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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 12:37:08
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
User closed query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Jan 2021 12:46:07
Query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' answered with 'UPDATED MEDICALLY ATTENDED AE TO YES' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 15:13:51
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 15:13:31
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	04 Jan 2021 15:13:31
User opened query 'Per sponsor review, SAE resulted in inpatient hospitalization. Please update field accordingly.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 14:59:08
DataPoint Verified.		07 Nov 2020 02:57:08
User entered 'No (N)'		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'No (N)'		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
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).		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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
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)	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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
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
User entered 'un:un' (non-conformant).	(b) (4), (b) (6)	17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4) (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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
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)	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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered empty.		17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
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)	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

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'Yes (Y)'		17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'		17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4)	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).		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 'I'	(b) (4), (b) (6)	17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '16 Aug 2020'		17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4)	
	(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).		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.		17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4) (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)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered empty.		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'		17 Aug 2020 20:17:31

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'Not Related (NOT RELATED)'		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'Not Related (NOT RELATED)'		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered 'None (NONE)'		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4)	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).		25 Aug 2020 16:35:31
User entered 'I'		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered '0'		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4)	
	(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).		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)'		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)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:57:08
User entered empty.		17 Aug 2020 20:17:31

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:31:05
User closed query 'please update narrative with all pertinent details' (Site from CRA).	(b) (4), (b) (6)	07 Nov 2020 02:57:21
DataPoint Verified.	(b) (4)	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

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Folder: Adverse Events

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[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 WHERE 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).		29 Sep 2020 16:21:05
User opened query 'PV Query: Please provide vital signs and physical exam findings.' (Site from Safety).		28 Sep 2020 16:18:33

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Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[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).		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).		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).		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).		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).		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
PRODUCTION RELEASE (v12.003 EAB) (1725)		1656 of 2045

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[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

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[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

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Amendment Manager: User entered 'I'	System	21 Aug 2020 02:09:40
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:09:37

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	04 Jan 2021 15:13:31
Amendment Manager: User entered '0'	System	21 Aug 2020 02:09:40
Amendment Manager inserted this DataPoint.	System	21 Aug 2020 02:09:37

US3412127

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:36:14

[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

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:36:14

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 13:19:19
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:06
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	14 Aug 2020 17:20:55

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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)	14 Aug 2020 17:23:27
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	14 Aug 2020 17:23:27
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'HYPERLIPIDEMIA'		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'once daily (QD)'		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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).		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

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Yes (Y)'		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'		14 Aug 2020 17:21:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'		14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '20'		14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	10 Nov 2020 22:07:19
	(b) (4), (b) (6)	
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: 09 Jun 2021 17:36:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'once daily (QD)'		14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'		14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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).		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: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'		14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:51:29
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' answered with 'subject has ongoing ptsd. This conmed is not for a corresponding AE.' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:40:02
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication. ' (Site from DM).	(b) (4), (b) (6)	04 Feb 2021 07:33:55
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: 09 Jun 2021 17:36:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'		14 Aug 2020 17:22:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'		14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '300'		14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'		14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'		14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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).		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: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'		14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Yes (Y)'		14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'		14 Aug 2020 17:22:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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-STEROIDS, 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	System	27 Oct 2020 17:37:40
Coding entries removed.	Jacob sekinger (b) (4) (b) (4)	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-STEROIDS, 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	System	14 Oct 2020 14:51:03
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	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-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 17:25:16

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by	Coder Import (b) (4)	14 Aug 2020 17:25:16
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	14 Aug 2020 17:24:26
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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'		14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User closed query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Jan 2021 15:37:08
Query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' answered with 'PER SOURCE DIARY SHEETS. SITE COULD NOT FIND ORIGINAL DIARY COPY. SUBI (b) (6) SIGNED 14-10-2020 TIO INDICATE MEDICATION WAS REVIEWED WITH SUBJECT ON 12-AUG-2020' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	12 Jan 2021 18:52:25
User opened query 'Per DM CLR: Note, there is no any corresponding data on Diary or AE that matches this Con Med indication during indicated timeframe. Please review Con Med use and add a medical condition and all applicable details to the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 21:02:06
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) (b) (4)	27 Oct 2020 17:37:45

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
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	(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
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: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '800'		14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'		14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'		14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		14 Aug 2020 17:24:05

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User closed 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) (4), (b) (6)	27 Nov 2020 08:06:48
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)	17 Nov 2020 08:18:56
DataPoint Verified.	(b) (4), (b) (6)	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)	14 Aug 2020 17:24:05

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:36:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
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: 09 Jun 2021 17:36:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
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: 09 Jun 2021 17:36:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:15
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: 09 Jun 2021 17:36:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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	System	23 Sep 2020 17:16:17
Coding entries removed.	(b) (4), (b) (6)	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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	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	(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: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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)'	(b) (4) 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: 09 Jun 2021 17:36:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: New Information		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)'	Mylene Asmar-Rios	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:36:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '19 Aug 2020' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
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: 09 Jun 2021 17:36:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
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: 09 Jun 2021 17:36:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:21
User entered '804 (804)'	System	18 Sep 2020 18:06:07

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: GLUCOCORTICOIDS, 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	System	23 Sep 2020 21:53:38
Coding entries removed.	(b) (4), (b) (6)	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: GLUCOCORTICOIDS, 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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'as needed (PRN)' reason for change:	Mylene Asmar-Rios	18 Sep 2020 18:46:15
Data Entry Error	(b) (4)	
User entered 'four times daily (QID)' reason for change: Data Entry Error	Mylene Asmar-Rios	18 Sep 2020 18:23:13
	(b) (4)	
User entered 'once daily (QD)'	Mylene 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: 09 Jun 2021 17:36:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
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: 09 Jun 2021 17:36:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
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: 09 Jun 2021 17:36:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:32
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: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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	System	23 Sep 2020 21:54:39
Coding entries removed.	(b) (4), (b) (6)	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	System	18 Sep 2020 18:29:11
User entered 'MUCINEX'	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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
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).		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: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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)'	(b) (4) 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: 09 Jun 2021 17:36:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: New Information		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: 09 Jun 2021 17:36:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '24 Aug 2020' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
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: 09 Jun 2021 17:36:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
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: 09 Jun 2021 17:36:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:36
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: 09 Jun 2021 17:36:14

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: GLUCOCORTICOIDS, 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	System	23 Sep 2020 21:56:43
Coding entries removed.	(b) (4), (b) (6)	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: GLUCOCORTICOIDS, 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	System	18 Sep 2020 18:34:32
User entered 'SOLUMEDROL'	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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: New Information		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: 09 Jun 2021 17:36:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '19 Aug 2020' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
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: 09 Jun 2021 17:36:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
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: 09 Jun 2021 17:36:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:27:58
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: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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	System	23 Sep 2020 21:57:44
Coding entries removed.	(b) (4), (b) (6)	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	System	18 Sep 2020 18:36:36
User entered 'ONDANSETRON'	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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'	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: 09 Jun 2021 17:36:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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 (b) (4)	18 Sep 2020 18:35:37

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:36:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'	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: 09 Jun 2021 17:36:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: New Information		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: 09 Jun 2021 17:36:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '19 Aug 2020' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
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: 09 Jun 2021 17:36:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
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: 09 Jun 2021 17:36:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:02
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: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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	System	23 Sep 2020 21:58:46
Coding entries removed.	(b) (4), (b) (6)	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	System	18 Sep 2020 18:37:42
User entered 'SODIUM CHLORIDE'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:37:14

PRODUCTION RELEASE (v12.003
EAB) (1725)

1827 of 2045

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)' reason for change: New Information		23 Sep 2020 21:58:11
User entered 'Yes (Y)'	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: 09 Jun 2021 17:36:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '19 Aug 2020' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
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: 09 Jun 2021 17:36:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
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: 09 Jun 2021 17:36:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:08
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: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
DataPoint Verified.		20 Apr 2021 22:34:51
User closed query 'Per DM CLR: Please review the dose recorded in the Name of medication as this is not the standard for this medication (e.g., 160mcg/4.5mcg). Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).		13 Apr 2021 13:20:14
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
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.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 07:59:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:59:54
Data point term sent to Coder	System	09 Apr 2021 14:52:08
Query 'Per DM CLR: Please review the dose recorded in the Name of medication as this is not the standard for this medication (e.g., 160mcg/4.5mcg). Please correct the dosage or provide explanation for alternate dosage. ' answered with 'this has been updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	09 Apr 2021 14:51:56
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	09 Apr 2021 14:51:36
User entered 'SYMBICORT (160 / 4.5 MCG)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	09 Apr 2021 14:51:36

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

Name of Medication

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the dose recorded in the Name of medication as this is not the standard for this medication (e.g., 160mcg/4.5mcg). Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 10:08:57
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)	17 Jan 2021 21:34:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Jan 2021 21:34:52
Data point term sent to Coder DataPoint Un-verified.	System	15 Jan 2021 19:38:36
	Melissa Fuson (b) (4)	15 Jan 2021 19:38:07
	(b) (4)	
Coding entries removed.	Melissa Fuson (b) (4)	15 Jan 2021 19:38:07
	(b) (4)	
User entered 'SYMBICORT (160 / 4.2 mcg)' reason for change: Data Entry Error DataPoint Verified.	Melissa Fuson (b) (4) (b) (4) (b) (4), (b) (6)	15 Jan 2021 19:38:07 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	System	23 Sep 2020 21:59:47

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	(b) (4), (b) (6)	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	System	18 Sep 2020 18:40:51
User entered 'SYMBICORT'	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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'acute respiratory failure' reason for change: New Information		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: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
DataPoint Verified.	(b) (4)	20 Apr 2021 22:34:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Un-verified.	(b) (4)	
	Melissa Fuson (b) (4)	15 Jan 2021 19:38:07
User entered '160 / 4.5' reason for change: Data Entry Error	(b) (4)	15 Jan 2021 19:38:07
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '160/4.5'	Mylene Asmar-Rios	18 Sep 2020 18:40:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:34:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User closed query 'Per CDM re-query: Per previous query, AE started on 14 AUG 2020 and ended on 20 AUG 2020. However the con med started on 26 AUG 2020 which is after the AE end date. It is unlikely to start a medication after the AE ended. Please reconcile the AE Start/stop date and Con med Start date and update as appropriate else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Feb 2021 15:51:54
Query 'Per CDM re-query: Per previous query, AE started on 14 AUG 2020 and ended on 20 AUG 2020. However the con med started on 26 AUG 2020 which is after the AE end date. It is unlikely to start a medication after the AE ended. Please reconcile the AE Start/stop date and Con med Start date and update as appropriate else clarify. ' answered with 'updated ' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:50:44
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:50:38
User entered '20 Aug 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:50:38
User closed query 'Per CDM re-query: Thank you for confirming the medication is still ongoing. However please review the start date of the medication (26AUG2020) is recorded after the corresponding AE has ended (20AUG2020). Please reconcile CM start date and AE start/end date and update as appropriate else please clarify. ' (Site from DM).	(b) (4), (b) (6)	20 Jan 2021 07:57:06
User opened query 'Per CDM re-query: Per previous query, AE started on 14 AUG 2020 and ended on 20 AUG 2020. However the con med started on 26 AUG 2020 which is after the AE end date. It is unlikely to start a medication after the AE ended. Please reconcile the AE Start/stop date and Con med Start date and update as appropriate else clarify. ' (Site from DM).		20 Jan 2021 07:57:03

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM re-query: Thank you for confirming the medication is still ongoing. However please review the start date of the medication (26AUG2020) is recorded after the corresponding AE has ended (20AUG2020). Please reconcile CM start date and AE start/end date and update as appropriate else please clarify. ' answered with 'updated medication and end date per source' (Site from DM).	Melissa Fuson (b) (4)	15 Jan 2021 19:38:43
User closed query 'Per DM CLR-RQ: Response noted. Please re-review as it is unusual for a medication to be given after the end date of a condition. Review start/end dates of AE and CM and update as appropriate. If used as a prophylaxis, please provide necessary ecrf updates. Else, provide further clarification. ' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 10:00:50
User opened query 'Per CDM re-query: Thank you for confirming the medication is still ongoing. However please review the start date of the medication (26AUG2020) is recorded after the corresponding AE has ended (20AUG2020). Please reconcile CM start date and AE start/end date and update as appropriate else please clarify. ' (Site from DM).		23 Dec 2020 10:00:47
Query 'Per DM CLR-RQ: Response noted. Please re-review as it is unusual for a medication to be given after the end date of a condition. Review start/end dates of AE and CM and update as appropriate. If used as a prophylaxis, please provide necessary ecrf updates. Else, provide further clarification. ' answered with 'INDICATION CHANGED TO ACUTE RESPIRATORY FAILURE. SUBI CALLED PATIENT AND STILL USING MEDICATION. PER NEW SOURCE' (Site from DM).	Melissa Fuson (b) (4)	22 Dec 2020 14:38:05
User opened query 'Per DM CLR-RQ: Response noted. Please re-review as it is unusual for a medication to be given after the end date of a condition. Review start/end dates of AE and CM and update as appropriate. If used as a prophylaxis, please provide necessary ecrf updates. Else, provide further clarification. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 13:42:55

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

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
		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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	Mylene Asmar-Rios (b) (4)	18 Sep 2020 18:40:02

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
DataPoint Verified.	(b) (4)	20 Apr 2021 22:34:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Un-verified.	(b) (4)	
	Melissa Fuson (b) (4)	15 Jan 2021 19:37:14
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Jan 2021 19:37:14
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	18 Sep 2020 18:40:02
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:36:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:34:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Un-verified.	(b) (4) Melissa Fuson (b) (4)	15 Jan 2021 19:37:14
User entered '12 Dec 2020' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	15 Jan 2021 19:37:14
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: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
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: 09 Jun 2021 17:36:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
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: 09 Jun 2021 17:36:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:28:15
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: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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)	23 Sep 2020 22:04:43
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Sep 2020 22:04:43
	(b) (4)	
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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Jan 2021 08:01:02
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' answered with 'updated per source has 2 puffs as needed by inh' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	15 Jan 2021 19:36:36
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication. Please correct the unit as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 21:02:34
DataPoint Verified.		10 Nov 2020 22:07:19
User entered 'acute respiratory failure'		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:34:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Un-verified.	(b) (4) Melissa Fuson (b) (4)	15 Jan 2021 19:36:12
User entered '2' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	15 Jan 2021 19:36:12
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) (b) (4)	30 Oct 2020 15:50:21
User entered '90' reason for change: Data Entry Error	Jacob sekinger (b) (4) (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: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:34:47
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Un-verified.	Melissa Fuson (b) (4)	15 Jan 2021 19:36:12
User entered 'puff (PUFF)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	15 Jan 2021 19:36:12
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: 09 Jun 2021 17:36:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'as needed (PRN)'		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '20 Aug 2020'		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Yes (Y)'		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'		23 Sep 2020 22:03:29

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	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: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
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) (4), (b) (6)	27 Nov 2020 08:09:09
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) (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.		10 Nov 2020 22:07:19
User entered 'Lumbar Pain'	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: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '300'	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: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'mg (mg)'	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: 09 Jun 2021 17:36:14

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:14

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Oral (ORAL)'	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: 09 Jun 2021 17:36:14

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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: 09 Jun 2021 17:36:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(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
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered '0'	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: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'Yes (Y)'	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: 09 Jun 2021 17:36:14

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered empty.	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: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 22:07:19
User entered 'No (N)'	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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[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: 09 Jun 2021 17:36:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Oct 2020 18:55:48

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.	(b) (4)	20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN, PRODUCTSYNONYM: LEVAQUIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 11:53:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Feb 2021 11:53:57
Data point term sent to Coder	System	11 Feb 2021 20:46:32
User entered 'levaquin'	Andrea Newlands (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered 'acute respiratory failure'	(b) (4) Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered '500'	(b) (4) Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered 'mg (mg)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	11 Feb 2021 20:45:39
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered 'once daily (QD)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	11 Feb 2021 20:45:39
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered 'Oral (ORAL)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	11 Feb 2021 20:45:39
	(b) (4)	

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Start date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered '16 Aug 2020'	(b) (4) Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered '23 Aug 2020'	(b) (4) Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
DataPoint Verified.		20 Apr 2021 22:34:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:17:15
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4) (b) (4)	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
User entered '1'	System	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
User entered '1'	System	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:36:14

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:29:27
User entered '804 (804)'	System	11 Feb 2021 20:45:39

US3412127

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:36:14

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:35:06
User entered 'No (N)'	(b) (4) (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: 09 Jun 2021 17:36:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
	(b) (4)	
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 17:29:58
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
	(b) (4)	

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	05 Jan 2021 17:29:54
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: 09 Jun 2021 17:36:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
Reviewed for Safety.	(b) (4)	05 Jan 2021 17:29:58
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
	(b) (4)	

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	05 Jan 2021 17:29:54
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: 09 Jun 2021 17:36:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		20 Sep 2020 20:19:11
User entered '1'		18 Aug 2020 13:06:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 17:29:58
DataPoint Verified.		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
	(b) (4)	

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	05 Jan 2021 17:29:54
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: 09 Jun 2021 17:36:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		24 Sep 2020 02:02:41
User entered '1'		20 Sep 2020 20:19:22

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	05 Jan 2021 17:29:58
DataPoint Verified.		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
	(b) (4)	

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	05 Jan 2021 17:29:54
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: 09 Jun 2021 17:36:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		02 Oct 2020 12:54:29
User entered '1'		24 Sep 2020 02:02:52

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
Reviewed for Safety.	(b) (4), (b) (6)	5 Jan 2021 17:29:58
DataPoint Verified.		7 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
	(b) (4)	

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	05 Jan 2021 17:29:54
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: 09 Jun 2021 17:36:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		15 Oct 2020 11:47:30
User entered 'I'		02 Oct 2020 12:54:40

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 17:29:58
DataPoint Verified.		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
	(b) (4)	

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	05 Jan 2021 17:29:54
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: 09 Jun 2021 17:36:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (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: 09 Jun 2021 17:36:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
Reviewed for Safety.	(b) (4), (b) (6)	05 Jan 2021 17:29:58
DataPoint Verified.		07 Nov 2020 02:56:46
User entered '1'		15 Oct 2020 11:47:39

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4)	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: 09 Jun 2021 17:36:14

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

Site Address: State

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
Reviewed for Safety.	(b) (4)	05 Jan 2021 17:29:58
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
	(b) (4)	

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form

Generated On: 09 Jun 2021 17:36:14

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	07 Nov 2020 02:56:46
Reviewed for Safety.		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: 09 Jun 2021 17:36:14

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	05 Jan 2021 17:29:54
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 (6)

Generated On: 09 Jun 2021 17:36:14

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:13:04
User entered '05/Jan/2021 12:29'	System	05 Jan 2021 17:29:54

US3412127

Folder: SAE USA-US061-2020-MRNA-1273-P301000001

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:36:14

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:31
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:13:04
Reviewed for Safety.		05 Jan 2021 17:29:58
User entered '1'		05 Jan 2021 17:29:54