

US3412059 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:29:39

All time stamps listed in this document are displayed in GMT

US3412059

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 13:54:52

Generated On: 09 Jun 2021 17:29:39

Participant ID

US3412059

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

US3412059

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:24:45

Generated On: 09 Jun 2021 17:29:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 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

US3412059

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:24:40

Generated On: 09 Jun 2021 17:29:39

Date of Birth (MMM yyyy)	(b) (6) 1951
Age	68
Age Units	YEARS
Age (Derived)	68
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

US3412059

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:24:40

Generated On: 09 Jun 2021 17:29:39

Date of Informed Consent (*dd MMM yyyy*) 31 JUL 2020

Month and Year of Informed Consent (derived) JUL 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

US3412059

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:24:45

Generated On: 09 Jun 2021 17:29:39

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3412059

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:24:45

Generated On: 09 Jun 2021 17:29:39

Were any significant conditions reported?

Yes ☒

No ☐

US3412059

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Mar 2021 19:28:29

Generated On: 09 Jun 2021 17:29:39

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2013
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 2013
Start Year (derived)	2013
Stop Month and Year (derived)	
Stop Year (derived)	

US3412059

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Mar 2021 19:28:29

Generated On: 09 Jun 2021 17:29:39

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412059

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Mar 2021 19:28:29

Generated On: 09 Jun 2021 17:29:39

Condition	SEASONAL ALLERGIES
Start date (dd MMM yyyy)	UN UNK 2015
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 2015
Start Year (derived)	2015
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412059

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Mar 2021 19:28:29

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Mar 2021 19:28:29

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Mar 2021 19:28:29

Generated On: 09 Jun 2021 17:29:39

Condition	LIPOMA RIGHT HIP
Start date (dd MMM yyyy)	UN UNK 2011
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 2011
Start Year (derived)	2011
Stop Month and Year (derived)	
Stop Year (derived)	

US3412059

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:24:45

Generated On: 09 Jun 2021 17:29:39

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	31 JUL 2020
Time of assessment (<i>00:00-23:59</i>)	08:51 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 08:51
Height (<i>xxx.x</i>)	170.5 cm
Weight (<i>xxx.x</i>)	81.3 kg
BMI (<i>xxx.x</i>)	27.96674 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412059

Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 04:24:45

Generated On: 09 Jun 2021 17:29:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

31 JUL 2020

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

US3412059

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:24:45

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:24:45

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	31 JUL 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

US3412059

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

What was the date of randomization? (dd MMM yyyy) 31 JUL 2020

What was the participant's randomization number? 184306

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 ☒

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Height	ND - Not Done
Weight	ND - Not Done

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

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)	31 JUL 2020
Time of assessment (00:00-23:59)	08:51 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 08:51
Temperature (xxx.x)	36.4 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

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)	31 JUL 2020
Time of assessment (00:00-23:59)	11:12 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 11:12
Temperature (xxx.x)	96.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	132 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3412059

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

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.

US3412059

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

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) 31 JUL 2020

What was the treatment time? (00:00-23:59) 10:10 (24 HR)

Treatment Date and Time (derived) 31 JUL 2020 10:10

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

US3412059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	31 JUL 2020
Collection time (00:00-23:59)	09:51 (24 HR)
Collection date and time (derived)	31 JUL 2020 09:51

US3412059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Collection date (dd MMM yyyy)			31 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	09:55	31 JUL 2020 09:55
Nasopharyngeal Swab 2	No		

US3412059

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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

96.3 °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 31 JUL 2020 11:22

PC Open Date & Time 31 JUL 2020 10:30

PC Close Date & Time 31 JUL 2020 13:00

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

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

31 JUL 2020 20:30

PC Open Date & Time

31 JUL 2020 13:55

PC Close Date & Time

01 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

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

96.6 °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

01 AUG 2020 20:11

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 20:17

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 20:17

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

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

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 20:09

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 21:00

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

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

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 20:32

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

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

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

31 JUL 2020 11:22

PC Open Date & Time

31 JUL 2020 10:30

PC Close Date & Time

31 JUL 2020 13:00

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

31 JUL 2020 20:31

PC Open Date & Time

31 JUL 2020 13:55

PC Close Date & Time

01 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

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)

6

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

01 AUG 2020 20:15

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

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

5

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

02 AUG 2020 20:19

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

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

3

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

03 AUG 2020 20:18

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

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

04 AUG 2020 20:09

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

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

05 AUG 2020 21:01

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

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

06 AUG 2020 20:33

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 11:23
PC Open Date & Time	31 JUL 2020 10:30
PC Close Date & Time	31 JUL 2020 13:00

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 20:31
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PC Open Date & Time	31 JUL 2020 13:55
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PC Close Date & Time	01 AUG 2020 11:59
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US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

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 ☒

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 20:15
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

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 ☒

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 20:20
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

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 ☒

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 20:18
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

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

53 of 2537

EAB) (1725)

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 20:10
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

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

55 of 2537

EAB) (1725)

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 21:06
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

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

57 of 2537

EAB) (1725)

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 20:33
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3412059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:24:40

Generated On: 09 Jun 2021 17:29:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

07 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412059

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:24:40

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:24:40

Generated On: 09 Jun 2021 17:29:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 14 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412059

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:24:40

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:24:40

Generated On: 09 Jun 2021 17:29:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 21 AUG 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412059

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:24:40

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	28 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	VISIT2

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

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)	28 AUG 2020
Time of assessment (00:00-23:59)	16:30 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 16:30
Temperature (xxx.x)	36.5 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 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)	84 mmHg
Diastolic Blood Pressure units	MMHG

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

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)	28 AUG 2020
Time of assessment (00:00-23:59)	17:52 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 17:52
Temperature (xxx.x)	98.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

28 AUG 2020

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

US3412059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

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) 28 AUG 2020

What was the treatment time? (00:00-23:59) 17:20 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 17:20

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

US3412059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

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

Collection date (dd MMM yyyy)	28 AUG 2020
-------------------------------	-------------

Collection time (00:00-23:59)	17:00 (24 HR)
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Collection date and time (derived)	28 AUG 2020 17:00
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US3412059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Collection date (dd MMM yyyy)			28 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	16:55	28 AUG 2020 16:55
Nasopharyngeal Swab 2	No		

US3412059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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

98.2 °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

28 AUG 2020 18:07

PC Open Date & Time

28 AUG 2020 17:40

PC Close Date & Time

28 AUG 2020 20:10

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

98.2 °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

29 AUG 2020 03:42

PC Open Date & Time

28 AUG 2020 21:05

PC Close Date & Time

29 AUG 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °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

29 AUG 2020 19:54

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

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 <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	30 AUG 2020 20:27
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 20:35

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 20:19

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

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

97.2 °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

02 SEP 2020 18:33

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

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

97.1 °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

03 SEP 2020 21:05

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

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

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

28 AUG 2020 18:07

PC Open Date & Time

28 AUG 2020 17:40

PC Close Date & Time

28 AUG 2020 20:10

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

29 AUG 2020 03:42

PC Open Date & Time

28 AUG 2020 21:05

PC Close Date & Time

29 AUG 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

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

29 AUG 2020 19:55

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

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

30 AUG 2020 20:27

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

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

31 AUG 2020 20:35

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

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

01 SEP 2020 20:20

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

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

02 SEP 2020 18:33

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

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

03 SEP 2020 21:06

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 18:08
PC Open Date & Time	28 AUG 2020 17:40
PC Close Date & Time	28 AUG 2020 20:10

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

No ☒

Yes ☐

PC Time stamp	29 AUG 2020 03:42
PC Open Date & Time	28 AUG 2020 21:05
PC Close Date & Time	29 AUG 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

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 ☒

PRODUCTION RELEASE (v12.003

93 of 2537

EAB) (1725)

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 19:55
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

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 ☒

PRODUCTION RELEASE (v12.003
EAB) (1725)

95 of 2537

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:28
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

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

97 of 2537

EAB) (1725)

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 20:36
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

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

99 of 2537

EAB) (1725)

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 20:20
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

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 ☒

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 18:34
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

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 ☒

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 21:06
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3412059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:24:40

Generated On: 09 Jun 2021 17:29:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

04 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412059

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:24:40

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 11 SEP 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412059

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

18 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412059

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	21 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	VISIT3

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

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) _____

US3412059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

21 SEP 2020

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

US3412059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	21 SEP 2020
Collection time (00:00-23:59)	8:40 (24 HR)
Collection date and time (derived)	21 SEP 2020 8:40

US3412059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:47:08

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	01 OCT 2020 08:43:11
Patient Cloud Open Date & Time	30 SEP 2020 00:01
Patient Cloud Close Date & Time	04 OCT 2020 23:59

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

08 OCT 2020 08:26:34

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

14 OCT 2020 13:02:02

Patient Cloud Open Date & Time

14 OCT 2020 00:01

Patient Cloud Close Date & Time

18 OCT 2020 23:59

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	29 OCT 2020 13:16:09
Patient Cloud Open Date & Time	28 OCT 2020 00:01
Patient Cloud Close Date & Time	01 NOV 2020 23:59

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 <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	04 NOV 2020 09:37:08
Patient Cloud Open Date & Time	04 NOV 2020 00:01
Patient Cloud Close Date & Time	08 NOV 2020 23:59

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 18:27:41

Patient Cloud Open Date & Time

11 NOV 2020 00:01

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

Have you been exposed to someone with known SARS-CoV-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 NOV 2020 12:17:31

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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	19 NOV 2020 16:30:16
Patient Cloud Open Date & Time	15 NOV 2020 00:01
Patient Cloud Close Date & Time	19 NOV 2020 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

22 NOV 2020 06:33:47

Patient Cloud Open Date & Time

22 NOV 2020 00:01

Patient Cloud Close Date & Time

26 NOV 2020 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 124

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 NOV 2020 12:53:39

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	06 DEC 2020 08:07:33
Patient Cloud Open Date & Time	06 DEC 2020 00:01
Patient Cloud Close Date & Time	10 DEC 2020 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

13 DEC 2020 14:29:58

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

20 DEC 2020 09:08:35

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 152

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

27 DEC 2020 09:24:19

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

03 JAN 2021 08:25:21

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 05:45:08
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

17 JAN 2021 09:03:23

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	24 JAN 2021 09:17:44
Patient Cloud Open Date & Time	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

31 JAN 2021 05:30:32

Patient Cloud Open Date & Time

31 JAN 2021 00:01

Patient Cloud Close Date & Time

04 FEB 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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	07 FEB 2021 13:14:29
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

14 FEB 2021 05:34:40

Patient Cloud Open Date & Time

14 FEB 2021 00:01

Patient Cloud Close Date & Time

18 FEB 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

21 FEB 2021 07:39:27

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

28 FEB 2021 17:45:52

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 222
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" 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"/>
Have 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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
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 checked="" 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 checked="" type="radio"/>
Date and time of submission	07 MAR 2021 22:57:54
Patient Cloud Open Date & Time	07 MAR 2021 00:01
Patient Cloud Close Date & Time	11 MAR 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 229
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	14 MAR 2021 08:34:38
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	21 MAR 2021 08:47:23
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

28 MAR 2021 08:52:41

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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	04 APR 2021 06:43:31
Patient Cloud Open Date & Time	04 APR 2021 00:01
Patient Cloud Close Date & Time	08 APR 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

11 APR 2021 08:20:16

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

18 APR 2021 09:10:19

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

25 APR 2021 09:43:23

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

Date and time of submission

02 MAY 2021 06:13:04

Patient Cloud Open Date & Time

02 MAY 2021 00:01

Patient Cloud Close Date & Time

06 MAY 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

13 MAY 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

27 MAY 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 <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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 313

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

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

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

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

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

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

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

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 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	24 JUN 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 334

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

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

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

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

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

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

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

08 JUL 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 <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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2021 00:01
Patient Cloud Close Date & Time	22 JUL 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 <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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

29 JUL 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

05 AUG 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

12 AUG 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 383

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
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Patient Cloud Close Date & Time	19 AUG 2021 23:59
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US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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="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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2021 00:01
Patient Cloud Close Date & Time	26 AUG 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 397

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

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

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

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

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

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

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2021 00:01
Patient Cloud Close Date & Time	09 SEP 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 SEP 2021 00:01
Patient Cloud Close Date & Time	23 SEP 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

30 SEP 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 432

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

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

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

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

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

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

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

07 OCT 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	14 OCT 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

21 OCT 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 <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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2021 00:01
Patient Cloud Close Date & Time	28 OCT 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 467

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

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

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

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

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

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

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 474
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 NOV 2021 00:01
Patient Cloud Close Date & Time	18 NOV 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 481
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

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 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

25 NOV 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
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Patient Cloud Close Date & Time	09 DEC 2021 23:59
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US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	19 DEC 2021 00:01
Patient Cloud Close Date & Time	23 DEC 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	30 DEC 2021 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 530

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

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

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

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

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

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

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

13 JAN 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

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 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

03 FEB 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

10 FEB 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 565

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

No ☐

Yes ☐

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

No ☐

Yes ☐

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

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

Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?

No ☐

Yes ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

17 FEB 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 FEB 2022 00:01
Patient Cloud Close Date & Time	24 FEB 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAR 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

06 MAR 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 593

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

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

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

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

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

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

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

17 MAR 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

24 MAR 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 607
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

31 MAR 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 635

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	28 APR 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 <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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 <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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

12 MAY 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 656
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

19 MAY 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 670
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

02 JUN 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

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 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

30 JUN 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 712

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	21 JUL 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 726
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUL 2022 00:01
Patient Cloud Close Date & Time	28 JUL 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT	DAY 733
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

11 AUG 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

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 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

25 AUG 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

[Patient Cloud Close Date & Time](#)

08 SEP 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

DAY 789

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

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

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

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

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

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

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

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 OCT 2022 00:01
Patient Cloud Close Date & Time	06 OCT 2022 23:59

US3412059

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:29:39

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		28 FEB 2021 01:58:52

US3412059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

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

SITE INADVERTENTLY MISSED
THIS CALL BECAUSE NOT
SCHEDULING IT IN THE CTMS

If Contact Not Made, please provide Comments

US3412059

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:28:29

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 NOV 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412059

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 28 DEC 2020

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412059

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 25 JAN 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412059

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

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

Visit date (dd MMM yyyy)	22 FEB 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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US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

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) _____

US3412059

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

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.

US3412059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 FEB 2021
Collection time (00:00-23:59)	09:40 (24 HR)
Collection date and time (derived)	22 FEB 2021 09:40

US3412059

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 23 MAR 2021

Please select one status for the follow-up contact
Contact Made ☒
Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412059

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 13:54:53

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412059

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412059

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:29:39

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"/>

US3412059

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:29:39

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412059

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 13:54:52

Generated On: 09 Jun 2021 17:29:39

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

Visit date (dd MMM yyyy)	18 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
------------	---------------

US3412059

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 13:54:52

Generated On: 09 Jun 2021 17:29:39

Date of updated informed consent (dd MMM yyyy) 18 JAN 2021

N/A - Subject Unblinded under Amendment 5 and Discontinued from Study False

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) 18 JAN 2021

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 _____

US3412059

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 13:54:52

Generated On: 09 Jun 2021 17:29:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00-23:59)	8:58 (24 HR)
Collection date and time (derived)	18 JAN 2021 8:58

US3412059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 13:54:52

Generated On: 09 Jun 2021 17:29:39

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	9:13
Collection Date and Time (derived)	18 JAN 2021 9:13

US3412059

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:27:23

Generated On: 09 Jun 2021 17:29:39

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

AEID

Adverse event

WORSENING OF RIGHT LOWER
EXTREMITY VASCULAR
INSUFFICIENCY

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

11 FEB 2021

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☒

No ☐

If not Ongoing, end date (dd MMM yyyy)

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

PRODUCTION RELEASE (v12.003

321 of 2537

EAB) (1725)

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

SUBJECT STATES TO HAVE
INCREASED EDEMA RIGHT
LOWER EXTREMITY. DUPLEX
SCAN VENOUS STUDY 11 FEB
2021, ONGOING, VASCULAR
SURGICAL CONSULTATION
PENDING. DUPLEX SCAN
REPORT REVIEWED BY
INVESTIGATOR ON SUBJECT
MOBILE DEVICE CONFIRMS
RIGHT LOWER EXTREMITY
VENOUS REFLUX.

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

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

AEID	USA-US061-2021-MRNA-1273-P30 1000014
Adverse event	ACUTE MYOCARDIAL INFARCTION
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)	6 MAR 2021
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)	06 MAR 2021
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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	06 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	08 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
PRODUCTION RELEASE (v12.003 EAB) (1725)	324 of 2537

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

SITE FOLLOWED UP WITH
E-DIARY REPORT ON
08-MAR-2021 AND WAS
NOTIFIED OF THE SUBJECT
BEEING SEEN AT AN ER ON
06-MAR-2021 FOR AN AMI. PER
SUBJECT AN IMMEDIATE
HEART CATH WAS
PERFORMED. 98% BLOCKAGE
IN LAD CORONARY ARTERY
WAS IDENTIFIED AND A STENT
WAS SUCCESSFULLY PLACED.
LATER THAT SAME DAY HE
STATES HE DEVELOPED CHEST
PAIN AGAIN. A SECOND HEART
CATH WAS PERFORMED, BUT
THE PHYSICIAN FELT ALL WAS
STABLE AND NO BLOCKAGES
NEEDED ADDRESSED. HIS IS TO
BE DISCHARGED 09-MAR-2021.
HE PLANS TO STAY IN OREGON
UNTIL 11-MAR-2021. HE STATES
THAT HE IS FEELING MUCH
BETTER AND IS BACK TO
BASELINE.
SUBJECT PRESENTED TO ED AS
A 69 Y/O MALE WITH HISTORY
OF HYPERLIPIDEMIA, HTN,
AND VASCULAR
INSUFFICIENCY, AND SUDDEN
ONSET SEVERE CHEST PAIN ON
06-MAR-2021. RECEIVED
BLINDED MRNA-1273 ON
03-JUL-20 AND 28-AUG-20.
INITIAL

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

PRESENTATION DIAPHERETIC,
ILL APPEARING, AND STABLE
VITALS SIGNS SA02 93%.
PHYSICAL EXAM WITH IN
NORMAL LIMITS. LABS: CBL/
BMP WNL, TROPONIN T 3.34
06-MAR-21, 1.54 07-MAR-21, EXG
ST ELEVATION 06-MAR-21,
COVID TEST NEGATIVE.
IMAGING: TTE 06-MAR-21,
CORONARY ANGIOGRAPH
WITH STENT PLACEMENT LAD.
SUBJECT RESPONDED WELL TO
PCI PROCEDURE THEN
PRESENTED WITH CHEST PAIN
SAME DAY AND CORONARY
ANGIOGRAPH WAS REPEATED.
SUBJECT IMPROVED AND WAS
DISCHARGED ON 08-MAR-2021

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

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

AEID	USA-US061-2021-MRNA-1273-P30 1000014
Adverse event	ACUTE SYSTOLIC 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)	06 MAR 2021
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)	08 MAR 2021
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)	06 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	08 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

328 of 2537

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

AEID	USA-US061-2021-MRNA-1273-P30 1000014
Adverse event	ISCHEMIC CARDIOMYOPATHY
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)	06 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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)	06 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	08 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

330 of 2537

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

AEID	USA-US061-2021-MRNA-1273-P30 1000014
Adverse event	PRECORDIAL CHEST PAIN
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)	06 MAR 2021
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)	06 MAR 2021
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)	06 MAR 2021
Hospital Discharge Date (dd MMM yyyy)	08 MAR 2021
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

PRODUCTION RELEASE (v12.003
EAB) (1725)

332 of 2537

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 30 Apr 2021 14:14:32

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:31:22

Generated On: 09 Jun 2021 17:29:39

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

Yes ☒

No ☐

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

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

335 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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 2018	
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

337 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	UN SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication CICLOPIROX (0.77%)

Prophylaxis Yes ☐
No ☒

Indication ONYCHOMYCOSIS - CREAM
FOR NAIL ENAMEL TOE
FUNGUS

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

339 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	UN	UNK 2019
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	15 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication FISH OIL

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 900

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

341 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN AUG 2020		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication CHOLESTOFF

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 900

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

343 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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 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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication HEADACHE SOLICITED AE

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 ☐

PRODUCTION RELEASE (v12.003

345 of 2537

EAB) (1725)

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)		30 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) 30 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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication ALLEGRA

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 180

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

347 of 2537

EAB) (1725)

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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 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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication SPIRONOLACTONE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

349 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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 2018
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy) UN NOV 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"/>	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

351 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

353 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication EZETIMIB E

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

355 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication MUCINEX

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIC
RHINITIS.

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

357 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	UN UNK 2018	
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication HEART HEALTH

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

359 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	09 MAR 2021	
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication CARVEDILOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION AND HEART HEALTH

Dose per administration 6.25

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

361 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)		09 MAR 2021
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication CLOPIDOGREL

Prophylaxis Yes ☐
No ☒

Indication HEART HEALTH

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

363 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	09 MAR 2021	
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication ISOSORBIDE MONONITRATE

Prophylaxis Yes ☐
No ☒

Indication HEART HEALTH

Dose per administration 30

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

365 of 2537

EAB) (1725)

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	09 MAR 2021	
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication HEART HEALTH/CHEST PAIN

Dose per administration 0.4

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
EAB) (1725)

367 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	09 MAR 2021	
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication AMI

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

369 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)		6 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 MAR 2021
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication VERSED

Prophylaxis Yes ☐
No ☒

Indication AMI

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

371 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)		6 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 MAR 2021
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication ZOFRAN

Prophylaxis Yes ☒
No ☐

Indication NAUSEA PROPHYLAXIS

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
EAB) (1725)

373 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	6 MAR 2021	
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"/>	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication LIDOCAINE 1%

Prophylaxis Yes ☐
No ☒

Indication PCI PROCEDURE

Dose per administration 10/1

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

375 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)		6 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 6 MAR 2021		
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication VERAPAMIL

Prophylaxis Yes ☐
No ☒

Indication PCI PROCEDURE

Dose per administration 5/10

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

377 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)		6 MAR 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		6 MAR 2021
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication PCI PROCEDURE

Dose per administration 150

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

379 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	06 MAR 2021	
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"/>	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication THROMBUS PROPHYLAXIS

Dose per administration 10,000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

381 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	06 MAR 2021	
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"/>	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication THROMBUS PROPHYLAXES

Dose per administration 2500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

383 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	06 MAR 2021	
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"/>	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication THROMBUS PROPHYLAXES

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

385 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 06 MAR 2021		
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication EPTIFIBATIDE

Prophylaxis Yes ☐
No ☒

Indication AMI

Dose per administration 14,292

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

387 of 2537

EAB) (1725)

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	06 MAR 2021	
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"/>	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication HEPARIN

Prophylaxis Yes ☒
No ☐

Indication THROMBUS PROPHYLACTIC

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

389 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)	06 MAR 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		06 MAR 2021
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"/>

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

Name of Medication ISOSORBIDE MONONITRATE

Prophylaxis Yes ☒
No ☐

Indication CHEST PAIN PROPHYLAXIS

Dose per administration 30

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

391 of 2537

EAB) (1725)

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 26 Apr 2021 14:39:15

Generated On: 09 Jun 2021 17:29:39

	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)		09 MAR 2021
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"/>

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:31:22

Generated On: 09 Jun 2021 17:29:39

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 16 Apr 2021 13:29:24

Generated On: 09 Jun 2021 17:29:39

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
11 FEB 2021	DUPLEX SCAN VENOUS STUDY	Adverse Event	
06 MAR 2021	ECG	Adverse Event	
06 MAR 2021	TRANSTHORACIC ECHO (TTE)	Adverse Event	
06 MAR 2021	CHEST XRAY	Adverse Event	
06 MAR 2021	CORONARY ANGIOGRAPHY WITH LV	Adverse Event	
06 MAR 2021	CARDIAC CATHETERIZATION	Adverse Event	
06 MAR 2021	COVID-19 SWAB	Adverse Event	

US3412059

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:29:39

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

US3412059

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:29:39

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 ☐

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 30 Apr 2021 17:22:02

Generated On: 09 Jun 2021 17:29:39

SAEID	USA-US061-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 30 Apr 2021 17:22:02

Generated On: 09 Jun 2021 17:29:39

SAEID	USA-US061-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	09/MAR/2021 11:18
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

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 30 Apr 2021 17:22:02

Generated On: 09 Jun 2021 17:29:39

SAEID	USA-US061-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	23/MAR/2021 11:10
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

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 30 Apr 2021 17:22:02

Generated On: 09 Jun 2021 17:29:39

SAEID	USA-US061-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	15/APR/2021 15:19
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

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Data signed: (b) (4) 30 Apr 2021 17:22:02

Generated On: 09 Jun 2021 17:29:39

SAEID	USA-US061-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	21/APR/2021 16:37
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Data signed: (b) (4) 30 Apr 2021 17:22:02

Generated On: 09 Jun 2021 17:29:39

SAEID	USA-US061-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	29/APR/2021 17:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (6)

Data signed: (b) (4) 30 Apr 2021 17:22:02

Generated On: 09 Jun 2021 17:29:39

SAEID	USA-US061-2021-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input 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	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	6
Date of submission (Pre-filled from custom function)	30/APR/2021 13:15
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

US3412059 (Prod: New Horizons Clinical Research)

US3412059

Form: Participant Creation

Generated On: 09 Jun 2021 17:29:39

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'US3412059'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 12:44:15

US3412059

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Jul 2020 14:03:14

US3412059

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 12:44:16

US3412059

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	31 Jul 2020 14:03:14

US3412059

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'SCRN'	System	31 Jul 2020 14:03:14

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered (b) (6) 1951'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 12:44:16

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '68'	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'YEARS'	System	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered '68'	System	31 Jul 2020 14:04:52

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Male (M)'	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'I'	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered empty.	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:39

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 14:03:47

US3412059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:39

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '31 Jul 2020'	Steven Anderson (b) (4)	31 Jul 2020 14:04:52

US3412059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'Jul 2020'	System	31 Jul 2020 14:04:52

US3412059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered '2020'	System	31 Jul 2020 14:04:52

US3412059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:39

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Amendment 1 (1)'	Steven Anderson (b) (4)	31 Jul 2020 14:04:52

US3412059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Jul 2020 14:04:52

US3412059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered empty.	Steven Anderson (b) (4)	31 Jul 2020 14:04:52

US3412059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:39

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered empty.	Steven Anderson (b) (4)	31 Jul 2020 14:04:52

US3412059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:39

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'No (N)'	Steven Anderson (b) (4)	31 Jul 2020 14:04:52

US3412059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:39

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 12:44:16

US3412059

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:39

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'I'	System	31 Jul 2020 14:05:01

US3412059

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Jul 2020 14:05:01

US3412059

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:29:39

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:28:19

US3412059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:39

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
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)	11 Aug 2020 22:28:42
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:42
Data point term sent to Coder	System	10 Aug 2020 20:28:59
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	10 Aug 2020 20:28:33

US3412059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'UN UNK 2013'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:28:33

US3412059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:28:33

US3412059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:28:33

US3412059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:28:33

US3412059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:28:33

US3412059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'Jan 2013'	System	10 Aug 2020 20:28:33

US3412059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered '2013'	System	10 Aug 2020 20:28:33

US3412059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	10 Aug 2020 20:28:33

US3412059

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	10 Aug 2020 20:28:33

US3412059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 22:28:59
Data point term sent to Coder	System	10 Aug 2020 20:28:59
User entered 'Hypertension'	(b) (4), (b) (6)	10 Aug 2020 20:28:51

US3412059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:28:51

US3412059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:28:51

US3412059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:28:51

US3412059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:28:51

US3412059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:28:51

US3412059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'Jan 2015'	System	10 Aug 2020 20:28:51

US3412059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered '2015'	System	10 Aug 2020 20:28:51

US3412059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	10 Aug 2020 20:28:51

US3412059

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	10 Aug 2020 20:28:51

US3412059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 13:32:32
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	19 Oct 2020 13:32:32
Data point term sent to Coder	System	19 Oct 2020 13:31:16
User entered 'Seasonal Allergies'	Steven Anderson (b) (4)	19 Oct 2020 13:30:39

US3412059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'un UNK 2015'	Steven Anderson (b) (4)	19 Oct 2020 13:30:39

US3412059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	Steven Anderson (b) (4)	19 Oct 2020 13:30:39

US3412059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Oct 2020 13:30:39

US3412059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 13:30:39

US3412059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	Steven Anderson (b) (4)	19 Oct 2020 13:30:39

US3412059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'Jan 2015'	System	19 Oct 2020 13:30:39

US3412059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered '2015'	System	19 Oct 2020 13:30:39

US3412059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	19 Oct 2020 13:30:39

US3412059

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	19 Oct 2020 13:30:39

US3412059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User coded data point as SOC: Infections and infestations, HLGT: Fungal infectious disorders, HLT: Fungal infections NEC, PT: Onychomycosis, LLT: Onychomycosis - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 22:50:57
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	10 Dec 2020 22:50:57
Data point term sent to Coder	System	08 Dec 2020 16:25:59
User entered 'ONYCHOMYCOSIS (B) FEET'	Melissa Fuson (b) (4)	08 Dec 2020 16:24:57

US3412059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'UN UNK 2019'	Melissa Fuson (b) (4)	08 Dec 2020 16:24:57

US3412059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 16:24:57

US3412059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	08 Dec 2020 16:24:57

US3412059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered empty.	(b) (4) Melissa Fuson (b) (4)	08 Dec 2020 16:24:57

US3412059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	Melissa Fuson (b) (4)	08 Dec 2020 16:24:57

US3412059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'Jan 2019'	System	08 Dec 2020 16:24:57

US3412059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered '2019'	System	08 Dec 2020 16:24:57

US3412059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	08 Dec 2020 16:24:57

US3412059

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	08 Dec 2020 16:24:57

US3412059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User coded data point as SOC: Vascular disorders, HLT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Vascular insufficiency, LLT: Vascular insufficiency - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 19:22:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	08 Mar 2021 19:22:40
Data point term sent to Coder	System	08 Mar 2021 19:22:06
User entered 'vascular insufficiency'	Steven Anderson (b) (4)	08 Mar 2021 19:21:21

US3412059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User entered 'un UNK 2017'	Steven Anderson (b) (4)	08 Mar 2021 19:21:21

US3412059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User entered '0'	Steven Anderson (b) (4)	08 Mar 2021 19:21:21

US3412059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Mar 2021 19:21:21

US3412059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User entered empty.	Steven Anderson (b) (4)	08 Mar 2021 19:21:21

US3412059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User entered '0'	Steven Anderson (b) (4)	08 Mar 2021 19:21:21

US3412059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'Jan 2017'	System	08 Mar 2021 19:21:21

US3412059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered '2017'	System	08 Mar 2021 19:21:21

US3412059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	08 Mar 2021 19:21:21

US3412059

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	08 Mar 2021 19:21:21

US3412059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:39

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User coded data point as SOC: Neoplasms benign, malignant and unspecified (incl cysts and polyps), HLGT: Soft tissue neoplasms benign, HLT: Soft tissue neoplasms benign NEC, PT: Lipoma, LLT: Lipoma - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 00:14:48
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	09 Mar 2021 00:14:48
Data point term sent to Coder	System	08 Mar 2021 19:22:07
User entered 'lipoma right hip'	Steven Anderson (b) (4)	08 Mar 2021 19:21:59

US3412059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User entered 'un UNK 2011'	Steven Anderson (b) (4)	08 Mar 2021 19:21:59

US3412059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User entered '0'	Steven Anderson (b) (4)	08 Mar 2021 19:21:59

US3412059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:39

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Mar 2021 19:21:59

US3412059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User entered empty.	Steven Anderson (b) (4)	08 Mar 2021 19:21:59

US3412059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:39

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User entered '0'	Steven Anderson (b) (4)	08 Mar 2021 19:21:59

US3412059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'Jan 2011'	System	08 Mar 2021 19:21:59

US3412059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered '2011'	System	08 Mar 2021 19:21:59

US3412059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	08 Mar 2021 19:21:59

US3412059

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered empty.	System	08 Mar 2021 19:21:59

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '08:51'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered '31 Jul 2020 08:51'	System	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '170.5' cm	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:31:18
DataPoint set to visible.	System	31 Jul 2020 14:05:01

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '81.3' kg	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:31:18
DataPoint set to visible.	System	31 Jul 2020 14:05:01

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
Amendment Manager: User entered '27.96674'	System	16 Sep 2020 23:39:29
User entered '28.0'	System	10 Aug 2020 20:31:18
DataPoint set to visible.	System	31 Jul 2020 14:05:01

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'kg/m2'	System	10 Aug 2020 20:31:18
DataPoint set to visible.	System	31 Jul 2020 14:05:01

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Aug 2020 15:13:56
User entered '36.4' C	(b) (4), (b) (6)	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 04:32:59
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:14:03
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 15:13:56
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:13:56
User entered 'Oral (Oral)'	(b) (4), (b) (6)	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Aug 2020 15:13:56
User entered '72'	(b) (4), (b) (6)	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'bpm'	System	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Aug 2020 15:13:56
User entered '18'	(b) (4), (b) (6)	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'breaths/min'	System	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Aug 2020 15:13:56
User entered '132'	(b) (4), (b) (6)	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'mmHg'	System	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	19 Aug 2020 15:13:56
User entered '78'	(b) (4), (b) (6)	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User entered 'mmHg'	System	10 Aug 2020 20:31:18

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59

US3412059

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59

US3412059

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:31:30

US3412059

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
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	28 Aug 2020 22:05:19
User entered '31 Jul 2020'	(b) (4), (b) (6)	10 Aug 2020 20:31:30

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

[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)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

[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)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

[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)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered '0'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'I'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:39

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:46:59
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:45
User entered 'Lives in high risk county'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:28

US3412059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Jul 2020 14:05:46

US3412059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '31 Jul 2020'	Steven Anderson (b) (4)	31 Jul 2020 14:05:46

US3412059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	31 Jul 2020 14:05:46

US3412059

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'VISIT1'	System	31 Jul 2020 14:05:46

US3412059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 14:04:13

US3412059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:39

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:27:46
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:27:46
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 14:04:13
User entered '184306' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 14:04:13

US3412059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 14:04:13

US3412059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:39

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)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'No (N)'	Steven Anderson (b) (4)	31 Jul 2020 14:06:36

US3412059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:39

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)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'No (N)'	Steven Anderson (b) (4)	31 Jul 2020 14:06:36

US3412059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'No (N)'	Steven Anderson (b) (4)	31 Jul 2020 14:06:36

US3412059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'No (N)'	Steven Anderson (b) (4)	31 Jul 2020 14:06:36

US3412059

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:39

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'No (N)'	Steven Anderson (b) (4)	31 Jul 2020 14:06:36

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:39

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User accepted default value 'Pre-Dose (PREDOSE)'		10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 15:19:41
User entered 'No (N)'	Mylene Asmar-Rios (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '31 Jul 2020' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 15:19:41
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '08:51' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 15:19:41
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered '31 Jul 2020 08:51'	System	19 Aug 2020 15:19:41
User entered empty.	System	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '36.4' C reason for change: Data Entry Error	(b) (4)	19 Aug 2020 15:19:41
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 15:19:41
User entered empty.	(b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '72' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 15:19:41
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Aug 2020 20:42:24
	(b) (4), (b) (6)	

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'bpm'	System	19 Aug 2020 15:19:41
User entered empty.	System	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '18' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 15:19:41
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'breaths/min'	System	19 Aug 2020 15:19:41
User entered empty.	System	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '132' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 15:19:41
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Aug 2020 20:42:24
	(b) (4), (b) (6)	

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'mmHg'	System	19 Aug 2020 15:19:41
User entered empty.	System	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '78' reason for change: Data Entry Error	(b) (4)	19 Aug 2020 15:19:41
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Aug 2020 20:42:24
	(b) (4), (b) (6)	

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'mmHg'	System	19 Aug 2020 15:19:41
User entered empty.	System	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:39

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:39

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User accepted default value 'Post-Dose (POSTDOSE)'		10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '11:12'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered '31 Jul 2020 11:12'	System	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User closed query 'Per CDM: Please indicate if this value should be considered as Clinically Significant or not. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Oct 2020 08:56:48
Query 'Per CDM: Please indicate if this value should be considered as Clinically Significant or not. ' answered with 'ncs' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Oct 2020 15:21:36
User closed query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3 Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	05 Oct 2020 05:14:50
User opened query 'Per CDM: Please indicate if this value should be considered as Clinically Significant or not. ' (Site from DM).		05 Oct 2020 05:14:48
Query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'per protocol, temperature within normal range.' (Site from System).	Jacob sekinger (b) (4) (b) (4)	30 Sep 2020 15:14:45
Amendment Manager: User opened query 'Temperature reported is out of range < 36C (96.8 F) per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	16 Sep 2020 23:39:29
User entered '96.3' F	(b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '68'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'bpm'	System	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '16'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'breaths/min'	System	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '132'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'mmHg'	System	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '68'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'mmHg'	System	10 Aug 2020 20:42:24

US3412059

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:42

US3412059

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:42

US3412059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Jul 2020 14:11:37

US3412059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Steven Anderson (b) (4)	31 Jul 2020 14:11:37

US3412059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

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)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Steven Anderson (b) (4)	31 Jul 2020 14:11:37

US3412059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 14:11:37

US3412059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '31 Jul 2020'	Steven Anderson (b) (4)	31 Jul 2020 14:11:37

US3412059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '10:10'	Steven Anderson (b) (4)	31 Jul 2020 14:11:37

US3412059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered '31 Jul 2020 10:10'	System	31 Jul 2020 14:11:37

US3412059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	31 Jul 2020 14:11:37

US3412059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'ONCE'	System	31 Jul 2020 14:11:37

US3412059

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 14:11:37

US3412059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:33:00

US3412059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:33:00

US3412059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '09:51'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:33:00

US3412059

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered '31 Jul 2020 09:51'	System	10 Aug 2020 20:33:00

US3412059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:29:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '31 Jul 2020'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:33:11

US3412059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		10 Aug 2020 20:33:11

US3412059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:33:11

US3412059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '09:55'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:33:11

US3412059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered '31 Jul 2020 09:55'	System	10 Aug 2020 20:33:11

US3412059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		10 Aug 2020 20:33:11

US3412059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:33:11

US3412059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:33:11

US3412059

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered empty.	System	10 Aug 2020 20:33:11

US3412059

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	10 Aug 2020 20:32:36

US3412059

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'I'	System	10 Aug 2020 20:32:36

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:21:53', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5c84052c-6b83-4995-81fc-bbc05e7cf536'	System	31 Jul 2020 15:22:28
User entered 'Yes (Y)'	System	31 Jul 2020 15:22:28

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:21:59', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5c84052c-6b83-4995-81fc-bbc05e7cf536'	System	31 Jul 2020 15:22:28
User entered '96.3'	System	31 Jul 2020 15:22:28

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:22:17', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5c84052c-6b83-4995-81fc-bbc05e7cf536'	System	31 Jul 2020 15:22:28
User entered 'No (N)'	System	31 Jul 2020 15:22:28

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:22:23', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5c84052c-6b83-4995-81fc-bbc05e7cf536' User entered '31 Jul 2020 11:22'	System	31 Jul 2020 15:22:28
	System	31 Jul 2020 15:22:28

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Jul 2020 10:30'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Jul 2020 13:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:30:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '9d0efff2-dc8f-4518-8121-3a9c00b6ece1'	System	01 Aug 2020 00:30:25
User entered 'Yes (Y)'	System	01 Aug 2020 00:30:25

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:30:08', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '9d0efff2-dc8f-4518-8121-3a9c00b6ece1' User entered '97.9'	System	01 Aug 2020 00:30:25
	System	01 Aug 2020 00:30:25

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:30:14', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '9d0efff2-dc8f-4518-8121-3a9c00b6ece1' User entered 'No (N)'	System	01 Aug 2020 00:30:25
	System	01 Aug 2020 00:30:25

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:30:23', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '9d0efff2-dc8f-4518-8121-3a9c00b6ece1'	System	01 Aug 2020 00:30:25
User entered '31 Jul 2020 20:30'	System	01 Aug 2020 00:30:25

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Jul 2020 13:55'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 2'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:11:10', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '026a6f31-98c1-45a5-a88e-d602ec3b82a1' User entered 'Yes (Y)'	System	02 Aug 2020 00:11:33
	System	02 Aug 2020 00:11:33

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:11:16', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '026a6f31-98c1-45a5-a88e-d602ec3b82a1' User entered '96.6'	System	02 Aug 2020 00:11:33
	System	02 Aug 2020 00:11:33

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:11:22', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '026a6f31-98c1-45a5-a88e-d602ec3b82a1' User entered 'No (N)'	System	02 Aug 2020 00:11:33
	System	02 Aug 2020 00:11:33

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:11:31', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '026a6f31-98c1-45a5-a88e-d602ec3b82a1' User entered '01 Aug 2020 20:11'	System	02 Aug 2020 00:11:33
	System	02 Aug 2020 00:11:33

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 3'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:16:45', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ad2d2c49-6c90-4eed-907b-1ed74396e580' User entered 'Yes (Y)'	System	03 Aug 2020 00:17:05
	System	03 Aug 2020 00:17:05

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:16:51', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ad2d2c49-6c90-4eed-907b-1ed74396e580' User entered '97.6'	System	03 Aug 2020 00:17:05
	System	03 Aug 2020 00:17:05

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:16:55', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ad2d2c49-6c90-4eed-907b-1ed74396e580' User entered 'No (N)'	System	03 Aug 2020 00:17:05
	System	03 Aug 2020 00:17:05

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:17:01', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ad2d2c49-6c90-4eed-907b-1ed74396e580'	System	03 Aug 2020 00:17:05
User entered '02 Aug 2020 20:17'	System	03 Aug 2020 00:17:05

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 4'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:17:28', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e1c097ab-cff3-49b4-a83d-dec49b0bf9a6' User entered 'Yes (Y)'	System	04 Aug 2020 00:17:47
	System	04 Aug 2020 00:17:47

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:17:34', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e1c097ab-cff3-49b4-a83d-dec49b0bf9a6' User entered '97.7'	System	04 Aug 2020 00:17:47
	System	04 Aug 2020 00:17:47

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:17:38', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e1c097ab-cff3-49b4-a83d-dec49b0bf9a6' User entered 'No (N)'	System	04 Aug 2020 00:17:47
	System	04 Aug 2020 00:17:47

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:17:44', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e1c097ab-cff3-49b4-a83d-dec49b0bf9a6' User entered '03 Aug 2020 20:17'	System	04 Aug 2020 00:17:47
	System	04 Aug 2020 00:17:47

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 5'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:09:20', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '82f92b3d-36f9-468c-ba83-a50adcf947a' User entered 'Yes (Y)'	System	05 Aug 2020 00:09:39
	System	05 Aug 2020 00:09:39

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:09:25', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '82f92b3d-36f9-468c-ba83-a50adcf947a' User entered '97.3'	System	05 Aug 2020 00:09:39
	System	05 Aug 2020 00:09:39

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:09:30', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '82f92b3d-36f9-468c-ba83-a50adcf947a'	System	05 Aug 2020 00:09:39
User entered 'No (N)'	System	05 Aug 2020 00:09:39

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:09:35', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '82f92b3d-36f9-468c-ba83-a50adcf947a'	System	05 Aug 2020 00:09:39
User entered '04 Aug 2020 20:09'	System	05 Aug 2020 00:09:39

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 6'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:00:17', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '812f13de-e71e-4076-a079-eef47a6ce52f' User entered 'Yes (Y)'	System	06 Aug 2020 01:00:43
	System	06 Aug 2020 01:00:43

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:00:24', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '812f13de-e71e-4076-a079-eef47a6ce52f' User entered '98.3'	System	06 Aug 2020 01:00:43
	System	06 Aug 2020 01:00:43

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:00:31', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '812f13de-e71e-4076-a079-eef47a6ce52f' User entered 'No (N)'	System	06 Aug 2020 01:00:43
	System	06 Aug 2020 01:00:43

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:00:42', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '812f13de-e71e-4076-a079-eef47a6ce52f' User entered '05 Aug 2020 21:00'	System	06 Aug 2020 01:00:43
	System	06 Aug 2020 01:00:43

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 7'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:32:41', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '31552bbb-d4e3-47cf-8674-1de24f0a4a18' User entered 'Yes (Y)'	System	07 Aug 2020 00:32:58
	System	07 Aug 2020 00:32:58

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:32:47', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '31552bbb-d4e3-47cf-8674-1de24f0a4a18' User entered '96.7'	System	07 Aug 2020 00:32:58
	System	07 Aug 2020 00:32:58

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:32:51', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '31552bbb-d4e3-47cf-8674-1de24f0a4a18' User entered 'No (N)'	System	07 Aug 2020 00:32:58
	System	07 Aug 2020 00:32:58

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:32:55', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '31552bbb-d4e3-47cf-8674-1de24f0a4a18' User entered '06 Aug 2020 20:32'	System	07 Aug 2020 00:32:58
	System	07 Aug 2020 00:32:58

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:22:33', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f8f4f534-af75-4c28-9681-62d4bf6d79fa'	System	31 Jul 2020 15:22:58
User entered 'None (1)'	System	31 Jul 2020 15:22:58

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:22:37', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f8f4f534-af75-4c28-9681-62d4bf6d79fa' User entered 'No (N)'	System	31 Jul 2020 15:22:58
	System	31 Jul 2020 15:22:58

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:22:42', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f8f4f534-af75-4c28-9681-62d4bf6d79fa' User entered 'No (N)'	System	31 Jul 2020 15:22:58
	System	31 Jul 2020 15:22:58

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:22:52', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f8f4f534-af75-4c28-9681-62d4bf6d79fa' User entered 'None (1)'	System	31 Jul 2020 15:22:58
	System	31 Jul 2020 15:22:58

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:22:56', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f8f4f534-af75-4c28-9681-62d4bf6d79fa' User entered '31 Jul 2020 11:22'	System	31 Jul 2020 15:22:58
	System	31 Jul 2020 15:22:58

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Jul 2020 10:30'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Jul 2020 13:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:30:44', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ca8260ea-79bf-47b2-a637-464a7323c384'	System	01 Aug 2020 00:31:03
User entered 'Does not interfere with activity (2)'	System	01 Aug 2020 00:31:03

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:30:47', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ca8260ea-79bf-47b2-a637-464a7323c384' User entered 'No (N)'	System	01 Aug 2020 00:31:03
	System	01 Aug 2020 00:31:03

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:30:51', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ca8260ea-79bf-47b2-a637-464a7323c384' User entered 'No (N)'	System	01 Aug 2020 00:31:03
	System	01 Aug 2020 00:31:03

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:30:55', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ca8260ea-79bf-47b2-a637-464a7323c384' User entered 'None (1)'	System	01 Aug 2020 00:31:03
	System	01 Aug 2020 00:31:03

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:31:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ca8260ea-79bf-47b2-a637-464a7323c384'	System	01 Aug 2020 00:31:03
User entered '31 Jul 2020 20:31'	System	01 Aug 2020 00:31:03

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Jul 2020 13:55'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 2'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:11:47', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5095575-0ef8-4c2f-8152-ba9fa766a245'	System	02 Aug 2020 00:15:09
User entered 'Does not interfere with activity (2)'	System	02 Aug 2020 00:15:09

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:11:52', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5095575-0ef8-4c2f-8152-ba9fa766a245'	System	02 Aug 2020 00:15:09
User entered 'No (N)'	System	02 Aug 2020 00:15:09

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:11:57', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5095575-0ef8-4c2f-8152-ba9fa766a245'	System	02 Aug 2020 00:15:09
User entered 'Yes (Y)'	System	02 Aug 2020 00:15:09

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:14:45', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5095575-0ef8-4c2f-8152-ba9fa766a245' User entered '6'	System	02 Aug 2020 00:15:09
	System	02 Aug 2020 00:15:09

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:14:54', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5095575-0ef8-4c2f-8152-ba9fa766a245' User entered 'None (1)'	System	02 Aug 2020 00:15:09
	System	02 Aug 2020 00:15:09

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:15:06', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5095575-0ef8-4c2f-8152-ba9fa766a245'	System	02 Aug 2020 00:15:09
User entered '01 Aug 2020 20:15'	System	02 Aug 2020 00:15:09

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 3'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:17:20', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5b0e97e6-4691-4c6f-99a5-a98788217f3c'	System	03 Aug 2020 00:19:49
User entered 'Does not interfere with activity (2)'	System	03 Aug 2020 00:19:49

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:19:04', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5b0e97e6-4691-4c6f-99a5-a98788217f3c' User entered 'No (N)'	System	03 Aug 2020 00:19:49
	System	03 Aug 2020 00:19:49

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:19:08', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5b0e97e6-4691-4c6f-99a5-a98788217f3c' User entered 'Yes (Y)'	System	03 Aug 2020 00:19:49
	System	03 Aug 2020 00:19:49

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:19:18', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5b0e97e6-4691-4c6f-99a5-a98788217f3c' User entered '5'	System	03 Aug 2020 00:19:49
	System	03 Aug 2020 00:19:49

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:19:25', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5b0e97e6-4691-4c6f-99a5-a98788217f3c' User entered 'None (1)'	System	03 Aug 2020 00:19:49
	System	03 Aug 2020 00:19:49

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:19:44', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5b0e97e6-4691-4c6f-99a5-a98788217f3c' User entered '02 Aug 2020 20:19'	System	03 Aug 2020 00:19:49
	System	03 Aug 2020 00:19:49

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 4'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:17:55', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '121042a9-abac-499b-a02b-b2213c787b48'	System	04 Aug 2020 00:18:29
User entered 'None (1)'	System	04 Aug 2020 00:18:29

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:17:58', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '121042a9-abac-499b-a02b-b2213c787b48' User entered 'No (N)'	System	04 Aug 2020 00:18:29
	System	04 Aug 2020 00:18:29

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:11', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '121042a9-abac-499b-a02b-b2213c787b48' User entered 'Yes (Y)'	System	04 Aug 2020 00:18:29
	System	04 Aug 2020 00:18:29

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:15', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '121042a9-abac-499b-a02b-b2213c787b48' User entered '3'	System	04 Aug 2020 00:18:29
	System	04 Aug 2020 00:18:29

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:19', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '121042a9-abac-499b-a02b-b2213c787b48' User entered 'None (1)'	System	04 Aug 2020 00:18:29
	System	04 Aug 2020 00:18:29

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:27', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '121042a9-abac-499b-a02b-b2213c787b48'	System	04 Aug 2020 00:18:29
User entered '03 Aug 2020 20:18'	System	04 Aug 2020 00:18:29

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 5'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:09:42', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4b0910d7-1a00-4228-a028-8423f926dcc0' User entered 'None (1)'	System	05 Aug 2020 00:10:02
	System	05 Aug 2020 00:10:02

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:09:46', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4b0910d7-1a00-4228-a028-8423f926dcc0'	System	05 Aug 2020 00:10:02
User entered 'No (N)'	System	05 Aug 2020 00:10:02

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:09:50', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4b0910d7-1a00-4228-a028-8423f926dcc0' User entered 'No (N)'	System	05 Aug 2020 00:10:02
	System	05 Aug 2020 00:10:02

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:09:54', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4b0910d7-1a00-4228-a028-8423f926dcc0' User entered 'None (1)'	System	05 Aug 2020 00:10:02
	System	05 Aug 2020 00:10:02

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:09:58', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4b0910d7-1a00-4228-a028-8423f926dcc0'	System	05 Aug 2020 00:10:02
User entered '04 Aug 2020 20:09'	System	05 Aug 2020 00:10:02

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 6'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:00:54', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3fd78b41-4458-4e71-9c67-7b60b94bddb1' User entered 'None (1)'	System	06 Aug 2020 01:01:25
	System	06 Aug 2020 01:01:25

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:01:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3fd78b41-4458-4e71-9c67-7b60b94bddb1' User entered 'No (N)'	System	06 Aug 2020 01:01:25
	System	06 Aug 2020 01:01:25

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:01:04', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3fd78b41-4458-4e71-9c67-7b60b94bddb1' User entered 'No (N)'	System	06 Aug 2020 01:01:25
	System	06 Aug 2020 01:01:25

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:01:13', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3fd78b41-4458-4e71-9c67-7b60b94bddb1' User entered 'None (1)'	System	06 Aug 2020 01:01:25
	System	06 Aug 2020 01:01:25

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:01:24', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3fd78b41-4458-4e71-9c67-7b60b94bddb1'	System	06 Aug 2020 01:01:25
User entered '05 Aug 2020 21:01'	System	06 Aug 2020 01:01:25

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 7'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f47c6aee-8fee-4a71-a736-9cd3a6a2f73a' User entered 'None (1)'	System	07 Aug 2020 00:33:17
	System	07 Aug 2020 00:33:17

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:03', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f47c6aee-8fee-4a71-a736-9cd3a6a2f73a' User entered 'No (N)'	System	07 Aug 2020 00:33:17
	System	07 Aug 2020 00:33:17

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:06', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f47c6aee-8fee-4a71-a736-9cd3a6a2f73a' User entered 'No (N)'	System	07 Aug 2020 00:33:17
	System	07 Aug 2020 00:33:17

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:12', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f47c6aee-8fee-4a71-a736-9cd3a6a2f73a' User entered 'None (1)'	System	07 Aug 2020 00:33:17
	System	07 Aug 2020 00:33:17

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:16', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f47c6aee-8fee-4a71-a736-9cd3a6a2f73a' User entered '06 Aug 2020 20:33'	System	07 Aug 2020 00:33:17
	System	07 Aug 2020 00:33:17

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:23:01', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5e54bbe-7e54-4745-b39e-e4516fedb92d' User entered 'None (0)'	System	31 Jul 2020 15:23:31
	System	31 Jul 2020 15:23:31

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:23:04', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5e54bbe-7e54-4745-b39e-e4516fedb92d' User entered 'None (0)'	System	31 Jul 2020 15:23:31
	System	31 Jul 2020 15:23:31

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:23:08', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5e54bbe-7e54-4745-b39e-e4516fedb92d' User entered 'None (0)'	System	31 Jul 2020 15:23:31
	System	31 Jul 2020 15:23:31

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:23:12', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5e54bbe-7e54-4745-b39e-e4516fedb92d' User entered 'None (0)'	System	31 Jul 2020 15:23:31
	System	31 Jul 2020 15:23:31

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:23:15', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5e54bbe-7e54-4745-b39e-e4516fedb92d' User entered 'None (0)'	System	31 Jul 2020 15:23:31
	System	31 Jul 2020 15:23:31

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:23:17', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5e54bbe-7e54-4745-b39e-e4516fedb92d' User entered 'None (0)'	System	31 Jul 2020 15:23:31
	System	31 Jul 2020 15:23:31

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:23:25', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5e54bbe-7e54-4745-b39e-e4516fedb92d' User entered 'No (N)'	System	31 Jul 2020 15:23:31
	System	31 Jul 2020 15:23:31

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T11:23:28', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f5e54bbe-7e54-4745-b39e-e4516fedb92d' User entered '31 Jul 2020 11:23'	System	31 Jul 2020 15:23:31
	System	31 Jul 2020 15:23:31

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Jul 2020 10:30'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Jul 2020 13:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:31:07', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '44e36879-1f2e-4b23-9603-b17b05ff16ec' User entered 'None (0)'	System	01 Aug 2020 00:31:44
	System	01 Aug 2020 00:31:44

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:31:11', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '44e36879-1f2e-4b23-9603-b17b05ff16ec' User entered 'None (0)'	System	01 Aug 2020 00:31:44
	System	01 Aug 2020 00:31:44

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:31:15', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '44e36879-1f2e-4b23-9603-b17b05ff16ec' User entered 'None (0)'	System	01 Aug 2020 00:31:44
	System	01 Aug 2020 00:31:44

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:31:19', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '44e36879-1f2e-4b23-9603-b17b05ff16ec' User entered 'None (0)'	System	01 Aug 2020 00:31:44
	System	01 Aug 2020 00:31:44

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:31:21', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '44e36879-1f2e-4b23-9603-b17b05ff16ec' User entered 'None (0)'	System	01 Aug 2020 00:31:44
	System	01 Aug 2020 00:31:44

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:31:25', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '44e36879-1f2e-4b23-9603-b17b05ff16ec' User entered 'None (0)'	System	01 Aug 2020 00:31:44
	System	01 Aug 2020 00:31:44

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:31:31', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '44e36879-1f2e-4b23-9603-b17b05ff16ec' User entered 'No (N)'	System	01 Aug 2020 00:31:44
	System	01 Aug 2020 00:31:44

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-07-31T20:31:43', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '44e36879-1f2e-4b23-9603-b17b05ff16ec' User entered '31 Jul 2020 20:31'	System	01 Aug 2020 00:31:44
	System	01 Aug 2020 00:31:44

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Jul 2020 13:55'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 2'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:15:12', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '80057c5b-8ea1-4bbf-93cc-922c1bd265b1' User entered 'None (0)'	System	02 Aug 2020 00:15:46
	System	02 Aug 2020 00:15:46

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:15:16', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '80057c5b-8ea1-4bbf-93cc-922c1bd265b1' User entered 'None (0)'	System	02 Aug 2020 00:15:46
	System	02 Aug 2020 00:15:46

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:15:21', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '80057c5b-8ea1-4bbf-93cc-922c1bd265b1' User entered 'None (0)'	System	02 Aug 2020 00:15:46
	System	02 Aug 2020 00:15:46

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:15:25', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '80057c5b-8ea1-4bbf-93cc-922c1bd265b1' User entered 'None (0)'	System	02 Aug 2020 00:15:46
	System	02 Aug 2020 00:15:46

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:15:28', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '80057c5b-8ea1-4bbf-93cc-922c1bd265b1' User entered 'None (0)'	System	02 Aug 2020 00:15:46
	System	02 Aug 2020 00:15:46

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:15:32', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '80057c5b-8ea1-4bbf-93cc-922c1bd265b1' User entered 'None (0)'	System	02 Aug 2020 00:15:46
	System	02 Aug 2020 00:15:46

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:15:37', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '80057c5b-8ea1-4bbf-93cc-922c1bd265b1' User entered 'No (N)'	System	02 Aug 2020 00:15:46
	System	02 Aug 2020 00:15:46

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-01T20:15:45', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '80057c5b-8ea1-4bbf-93cc-922c1bd265b1' User entered '01 Aug 2020 20:15'	System	02 Aug 2020 00:15:46
	System	02 Aug 2020 00:15:46

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 3'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:19:50', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '341d364b-6872-4077-a79e-145b282b4950'	System	03 Aug 2020 00:20:43
User entered 'None (0)'	System	03 Aug 2020 00:20:43

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:19:54', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '341d364b-6872-4077-a79e-145b282b4950'	System	03 Aug 2020 00:20:43
User entered 'None (0)'	System	03 Aug 2020 00:20:43

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:19:58', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '341d364b-6872-4077-a79e-145b282b4950'	System	03 Aug 2020 00:20:43
User entered 'None (0)'	System	03 Aug 2020 00:20:43

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:20:03', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '341d364b-6872-4077-a79e-145b282b4950'	System	03 Aug 2020 00:20:43
User entered 'None (0)'	System	03 Aug 2020 00:20:43

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:20:12', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '341d364b-6872-4077-a79e-145b282b4950' User entered 'None (0)'	System	03 Aug 2020 00:20:43
	System	03 Aug 2020 00:20:43

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:20:31', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '341d364b-6872-4077-a79e-145b282b4950'	System	03 Aug 2020 00:20:43
User entered 'None (0)'	System	03 Aug 2020 00:20:43

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:20:36', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '341d364b-6872-4077-a79e-145b282b4950'	System	03 Aug 2020 00:20:43
User entered 'No (N)'	System	03 Aug 2020 00:20:43

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-02T20:20:41', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '341d364b-6872-4077-a79e-145b282b4950'	System	03 Aug 2020 00:20:43
User entered '02 Aug 2020 20:20'	System	03 Aug 2020 00:20:43

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 4'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:31', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4414a43e-a664-46a2-8cbf-12e766e189b1' User entered 'None (0)'	System	04 Aug 2020 00:18:57
	System	04 Aug 2020 00:18:57

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:34', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4414a43e-a664-46a2-8cbf-12e766e189b1' User entered 'None (0)'	System	04 Aug 2020 00:18:57
	System	04 Aug 2020 00:18:57

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:37', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4414a43e-a664-46a2-8cbf-12e766e189b1' User entered 'None (0)'	System	04 Aug 2020 00:18:57
	System	04 Aug 2020 00:18:57

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:40', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4414a43e-a664-46a2-8cbf-12e766e189b1' User entered 'None (0)'	System	04 Aug 2020 00:18:57
	System	04 Aug 2020 00:18:57

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:42', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4414a43e-a664-46a2-8cbf-12e766e189b1' User entered 'None (0)'	System	04 Aug 2020 00:18:57
	System	04 Aug 2020 00:18:57

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:45', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4414a43e-a664-46a2-8cbf-12e766e189b1' User entered 'None (0)'	System	04 Aug 2020 00:18:57
	System	04 Aug 2020 00:18:57

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:49', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4414a43e-a664-46a2-8cbf-12e766e189b1' User entered 'No (N)'	System	04 Aug 2020 00:18:57
	System	04 Aug 2020 00:18:57

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-03T20:18:56', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4414a43e-a664-46a2-8cbf-12e766e189b1' User entered '03 Aug 2020 20:18'	System	04 Aug 2020 00:18:57
	System	04 Aug 2020 00:18:57

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 5'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:10:02', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e6235316-2aba-44b6-80a6-9c7247df4603'	System	05 Aug 2020 00:10:37
User entered 'None (0)'	System	05 Aug 2020 00:10:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:10:05', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e6235316-2aba-44b6-80a6-9c7247df4603'	System	05 Aug 2020 00:10:37
User entered 'None (0)'	System	05 Aug 2020 00:10:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:10:09', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e6235316-2aba-44b6-80a6-9c7247df4603'	System	05 Aug 2020 00:10:37
User entered 'None (0)'	System	05 Aug 2020 00:10:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:10:12', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e6235316-2aba-44b6-80a6-9c7247df4603'	System	05 Aug 2020 00:10:37
User entered 'None (0)'	System	05 Aug 2020 00:10:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:10:15', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e6235316-2aba-44b6-80a6-9c7247df4603'	System	05 Aug 2020 00:10:37
User entered 'None (0)'	System	05 Aug 2020 00:10:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:10:18', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e6235316-2aba-44b6-80a6-9c7247df4603'	System	05 Aug 2020 00:10:37
User entered 'None (0)'	System	05 Aug 2020 00:10:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:10:22', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e6235316-2aba-44b6-80a6-9c7247df4603' User entered 'No (N)'	System	05 Aug 2020 00:10:37
	System	05 Aug 2020 00:10:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-04T20:10:36', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e6235316-2aba-44b6-80a6-9c7247df4603'	System	05 Aug 2020 00:10:37
User entered '04 Aug 2020 20:10'	System	05 Aug 2020 00:10:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 6'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:05:43', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5da0f3a7-61ba-46af-8fa4-5656d1b42630' User entered 'None (0)'	System	06 Aug 2020 01:06:38
	System	06 Aug 2020 01:06:38

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:05:58', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5da0f3a7-61ba-46af-8fa4-5656d1b42630' User entered 'None (0)'	System	06 Aug 2020 01:06:38
	System	06 Aug 2020 01:06:38

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:06:05', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5da0f3a7-61ba-46af-8fa4-5656d1b42630' User entered 'None (0)'	System	06 Aug 2020 01:06:38
	System	06 Aug 2020 01:06:38

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:06:11', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5da0f3a7-61ba-46af-8fa4-5656d1b42630' User entered 'None (0)'	System	06 Aug 2020 01:06:38
	System	06 Aug 2020 01:06:38

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:06:16', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5da0f3a7-61ba-46af-8fa4-5656d1b42630' User entered 'None (0)'	System	06 Aug 2020 01:06:38
	System	06 Aug 2020 01:06:38

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:06:24', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5da0f3a7-61ba-46af-8fa4-5656d1b42630' User entered 'None (0)'	System	06 Aug 2020 01:06:38
	System	06 Aug 2020 01:06:38

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:06:30', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5da0f3a7-61ba-46af-8fa4-5656d1b42630'	System	06 Aug 2020 01:06:38
User entered 'No (N)'	System	06 Aug 2020 01:06:38

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-05T21:06:33', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5da0f3a7-61ba-46af-8fa4-5656d1b42630'	System	06 Aug 2020 01:06:38
User entered '05 Aug 2020 21:06'	System	06 Aug 2020 01:06:38

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 7'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:19', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cb2b6208-ce5d-4a73-afc9-ee4d120b0200'	System	07 Aug 2020 00:33:50
User entered 'None (0)'	System	07 Aug 2020 00:33:50

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:22', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cb2b6208-ce5d-4a73-afc9-ee4d120b0200'	System	07 Aug 2020 00:33:50
User entered 'None (0)'	System	07 Aug 2020 00:33:50

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:24', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cb2b6208-ce5d-4a73-afc9-ee4d120b0200'	System	07 Aug 2020 00:33:50
User entered 'None (0)'	System	07 Aug 2020 00:33:50

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:26', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cb2b6208-ce5d-4a73-afc9-ee4d120b0200'	System	07 Aug 2020 00:33:50
User entered 'None (0)'	System	07 Aug 2020 00:33:50

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:29', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cb2b6208-ce5d-4a73-afc9-ee4d120b0200' User entered 'None (0)'	System	07 Aug 2020 00:33:50
	System	07 Aug 2020 00:33:50

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:31', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cb2b6208-ce5d-4a73-afc9-ee4d120b0200'	System	07 Aug 2020 00:33:50
User entered 'None (0)'	System	07 Aug 2020 00:33:50

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:37', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cb2b6208-ce5d-4a73-afc9-ee4d120b0200' User entered 'No (N)'	System	07 Aug 2020 00:33:50
	System	07 Aug 2020 00:33:50

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-06T20:33:47', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cb2b6208-ce5d-4a73-afc9-ee4d120b0200'	System	07 Aug 2020 00:33:50
User entered '06 Aug 2020 20:33'	System	07 Aug 2020 00:33:50

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 14:11:37

US3412059

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:04:31

US3412059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '07 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:04:31

US3412059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:04:31

US3412059

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:04:31

US3412059

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:04:35

US3412059

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'I'	System	28 Aug 2020 22:04:35

US3412059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:04:47

US3412059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '14 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:04:47

US3412059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:04:47

US3412059

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered empty.	(b) (4)	28 Aug 2020 22:04:47
	(b) (4), (b) (6)	

US3412059

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:04:51

US3412059

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:00
User entered 'I'	System	28 Aug 2020 22:04:51

US3412059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:05:04

US3412059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:05:04

US3412059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:05:04

US3412059

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:05:04

US3412059

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:05:09

US3412059

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User entered 'I'	System	28 Aug 2020 22:05:09

US3412059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:05:19

US3412059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:05:19

US3412059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[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 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:05:19

US3412059

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'VISIT2'	System	28 Aug 2020 22:05:19

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User accepted default value 'Pre-Dose (PREDOSE)'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '28 Aug 2020'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '16:30'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered '28 Aug 2020 16:30'	System	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '36.5' C	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '60'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'bpm'	System	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '12'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'breaths/min'	System	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '124'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'mmHg'	System	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '84'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'mmHg'	System	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User accepted default value 'Post-Dose (POSTDOSE)'	Jacob sekinger (b) (4) (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '28 Aug 2020'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '17:52'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered '28 Aug 2020 17:52'	System	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '98.2' F	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Oral (Oral)'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '60'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'bpm'	System	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '14'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'breaths/min'	System	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '128'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'mmHg'	System	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '80'	Jacob sekinger (b) (4)	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'mmHg'	System	30 Sep 2020 15:18:47

US3412059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:05:32

US3412059

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:05:32

US3412059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User closed query 'Per CDM: please complete all the applicable pages in Visit 2' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 18:20:45
Query 'Per CDM: please complete all the applicable pages in Visit 2' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	30 Sep 2020 15:19:05
User opened query 'Per CDM: please complete all the applicable pages in Visit 2' (Site from DM).	(b) (4), (b) (6)	22 Sep 2020 15:55:25
User entered 'Yes (Y)'		28 Aug 2020 22:06:03

US3412059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:06:03

US3412059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:06:03

US3412059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 22:06:03

US3412059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '28 Aug 2020'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:06:03

US3412059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '17:20'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:06:03

US3412059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered '28 Aug 2020 17:20'	System	28 Aug 2020 22:06:03

US3412059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	28 Aug 2020 22:06:03

US3412059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'ONCE'	System	28 Aug 2020 22:06:03

US3412059

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:39

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 22:06:03

US3412059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	30 Sep 2020 15:16:43

US3412059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '28 Aug 2020'	Jacob sekinger (b) (4)	30 Sep 2020 15:16:43

US3412059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '17:00'	Jacob sekinger (b) (4)	30 Sep 2020 15:16:43

US3412059

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered '28 Aug 2020 17:00'	System	30 Sep 2020 15:16:43

US3412059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:29:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '28 Aug 2020'	Jacob sekinger (b) (4)	30 Sep 2020 15:17:06

US3412059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Jacob sekinger (b) (4)	30 Sep 2020 15:17:06

US3412059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	30 Sep 2020 15:17:06

US3412059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '16:55'	Jacob sekinger (b) (4)	30 Sep 2020 15:17:06

US3412059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered '28 Aug 2020 16:55'	System	30 Sep 2020 15:17:06

US3412059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:39

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Jacob sekinger (b) (4)	30 Sep 2020 15:17:06

US3412059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'No (N)'	Jacob sekinger (b) (4)	30 Sep 2020 15:17:06

US3412059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:39

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:17:06

US3412059

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered empty.	System	30 Sep 2020 15:17:06

US3412059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:34:06

US3412059

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered '1'	System	04 Sep 2020 12:34:06

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:06:47', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '31383695-5d9c-46cf-8df0-8ac0ed82af15'	System	28 Aug 2020 22:07:23
User entered 'Yes (Y)'	System	28 Aug 2020 22:07:23

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:06:56', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '31383695-5d9c-46cf-8df0-8ac0ed82af15' User entered '98.2'	System	28 Aug 2020 22:07:23
	System	28 Aug 2020 22:07:23

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:15', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '31383695-5d9c-46cf-8df0-8ac0ed82af15'	System	28 Aug 2020 22:07:23
User entered 'No (N)'	System	28 Aug 2020 22:07:23

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:21', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '31383695-5d9c-46cf-8df0-8ac0ed82af15'	System	28 Aug 2020 22:07:23
User entered '28 Aug 2020 18:07'	System	28 Aug 2020 22:07:23

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '28 Aug 2020 17:40'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '28 Aug 2020 20:10'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:02', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f0b3ec16-f088-460e-ba12-e43739b66855'	System	29 Aug 2020 07:42:20
User entered 'Yes (Y)'	System	29 Aug 2020 07:42:20

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:08', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f0b3ec16-f088-460e-ba12-e43739b66855' User entered '98.2'	System	29 Aug 2020 07:42:20
	System	29 Aug 2020 07:42:20

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:13', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f0b3ec16-f088-460e-ba12-e43739b66855'	System	29 Aug 2020 07:42:20
User entered 'No (N)'	System	29 Aug 2020 07:42:20

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:18', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f0b3ec16-f088-460e-ba12-e43739b66855' User entered '29 Aug 2020 03:42'	System	29 Aug 2020 07:42:20
	System	29 Aug 2020 07:42:20

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '28 Aug 2020 21:05'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 2'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:54:25', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '45d3c385-3c02-43d3-aa88-d6250adc557f'	System	29 Aug 2020 23:54:46
User entered 'Yes (Y)'	System	29 Aug 2020 23:54:46

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:54:34', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '45d3c385-3c02-43d3-aa88-d6250adc557f' User entered '97.5'	System	29 Aug 2020 23:54:46
	System	29 Aug 2020 23:54:46

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:54:38', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '45d3c385-3c02-43d3-aa88-d6250adc557f'	System	29 Aug 2020 23:54:46
User entered 'No (N)'	System	29 Aug 2020 23:54:46

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:54:44', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '45d3c385-3c02-43d3-aa88-d6250adc557f' User entered '29 Aug 2020 19:54'	System	29 Aug 2020 23:54:46
	System	29 Aug 2020 23:54:46

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 3'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:27:01', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c74bcaf7-3b4f-4ee7-9374-02249f2f726f' User entered 'Yes (Y)'	System	31 Aug 2020 00:29:20
	System	31 Aug 2020 00:29:20

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:27:08', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c74bcaf7-3b4f-4ee7-9374-02249f2f726f' User entered '97.4'	System	31 Aug 2020 00:29:20
	System	31 Aug 2020 00:29:20

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:27:15', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c74bcaf7-3b4f-4ee7-9374-02249f2f726f' User entered 'Yes (Y)'	System	31 Aug 2020 00:29:20
	System	31 Aug 2020 00:29:20

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'CONTACT' (Site from System).	(b) (4), (b) (6)	15 Oct 2020 04:15:45
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios	02 Oct 2020 15:32:06
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:27:24', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c74bcaf7-3b4f-4ee7-9374-02249f2f726f'	(b) (4)	
User entered '1'	System	31 Aug 2020 00:29:20
	System	31 Aug 2020 00:29:20
	System	31 Aug 2020 00:29:20

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:27:24', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c74bcaf7-3b4f-4ee7-9374-02249f2f726f' User entered '0'	System	31 Aug 2020 00:29:20
	System	31 Aug 2020 00:29:20

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:27:36', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c74bcaf7-3b4f-4ee7-9374-02249f2f726f' User entered '30 Aug 2020 20:27'	System	31 Aug 2020 00:29:20
	System	31 Aug 2020 00:29:20

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 4'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:35:06', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '54cac4a2-5bca-4655-a4f5-c981b20b1085' User entered 'Yes (Y)'	System	01 Sep 2020 00:35:32
	System	01 Sep 2020 00:35:32

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:35:15', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '54cac4a2-5bca-4655-a4f5-c981b20b1085' User entered '96.7'	System	01 Sep 2020 00:35:32
	System	01 Sep 2020 00:35:32

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:35:19', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '54cac4a2-5bca-4655-a4f5-c981b20b1085' User entered 'No (N)'	System	01 Sep 2020 00:35:32
	System	01 Sep 2020 00:35:32

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:35:27', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '54cac4a2-5bca-4655-a4f5-c981b20b1085'	System	01 Sep 2020 00:35:32
User entered '31 Aug 2020 20:35'	System	01 Sep 2020 00:35:32

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 5'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:19:35', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '61e777f2-9f7e-4fab-a320-906b33baa5ca' User entered 'Yes (Y)'	System	02 Sep 2020 00:19:52
	System	02 Sep 2020 00:19:52

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:19:41', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '61e777f2-9f7e-4fab-a320-906b33baa5ca' User entered '96.8'	System	02 Sep 2020 00:19:52
	System	02 Sep 2020 00:19:52

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:19:44', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '61e777f2-9f7e-4fab-a320-906b33baa5ca' User entered 'No (N)'	System	02 Sep 2020 00:19:52
	System	02 Sep 2020 00:19:52

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:19:49', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '61e777f2-9f7e-4fab-a320-906b33baa5ca' User entered '01 Sep 2020 20:19'	System	02 Sep 2020 00:19:52
	System	02 Sep 2020 00:19:52

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 6'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:33:20', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4624a498-800c-45ad-8c6a-9b7ee0dda99d' User entered 'Yes (Y)'	System	02 Sep 2020 22:33:37
	System	02 Sep 2020 22:33:37

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:33:25', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4624a498-800c-45ad-8c6a-9b7ee0dda99d' User entered '97.2'	System	02 Sep 2020 22:33:37
	System	02 Sep 2020 22:33:37

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:33:29', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4624a498-800c-45ad-8c6a-9b7ee0dda99d' User entered 'No (N)'	System	02 Sep 2020 22:33:37
	System	02 Sep 2020 22:33:37

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:33:34', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4624a498-800c-45ad-8c6a-9b7ee0dda99d' User entered '02 Sep 2020 18:33'	System	02 Sep 2020 22:33:37
	System	02 Sep 2020 22:33:37

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 7'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:05:37', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e3379b4b-e538-4fa8-8f0c-95027d2b8e62' User entered 'Yes (Y)'	System	04 Sep 2020 01:05:52
	System	04 Sep 2020 01:05:52

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:05:43', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e3379b4b-e538-4fa8-8f0c-95027d2b8e62' User entered '97.1'	System	04 Sep 2020 01:05:52
	System	04 Sep 2020 01:05:52

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:05:46', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e3379b4b-e538-4fa8-8f0c-95027d2b8e62' User entered 'No (N)'	System	04 Sep 2020 01:05:52
	System	04 Sep 2020 01:05:52

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:05:50', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e3379b4b-e538-4fa8-8f0c-95027d2b8e62'	System	04 Sep 2020 01:05:52
User entered '03 Sep 2020 21:05'	System	04 Sep 2020 01:05:52

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:28', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '6b0a1805-045b-4dce-a8fb-f21444509ff8'	System	28 Aug 2020 22:07:48
User entered 'None (1)'	System	28 Aug 2020 22:07:48

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:32', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '6b0a1805-045b-4dce-a8fb-f21444509ff8'	System	28 Aug 2020 22:07:48
User entered 'No (N)'	System	28 Aug 2020 22:07:48

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:35', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '6b0a1805-045b-4dce-a8fb-f21444509ff8'	System	28 Aug 2020 22:07:48
User entered 'No (N)'	System	28 Aug 2020 22:07:48

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:40', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '6b0a1805-045b-4dce-a8fb-f21444509ff8'	System	28 Aug 2020 22:07:48
User entered 'None (1)'	System	28 Aug 2020 22:07:48

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:45', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '6b0a1805-045b-4dce-a8fb-f21444509ff8'	System	28 Aug 2020 22:07:48
User entered '28 Aug 2020 18:07'	System	28 Aug 2020 22:07:48

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '28 Aug 2020 17:40'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '28 Aug 2020 20:10'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:22', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e58b831-24d9-46b5-bde4-13130bcb024c'	System	29 Aug 2020 07:42:35
User entered 'None (1)'	System	29 Aug 2020 07:42:35

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:25', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e58b831-24d9-46b5-bde4-13130bcb024c'	System	29 Aug 2020 07:42:35
User entered 'No (N)'	System	29 Aug 2020 07:42:35

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:29', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e58b831-24d9-46b5-bde4-13130bcb024c' User entered 'No (N)'	System	29 Aug 2020 07:42:35
	System	29 Aug 2020 07:42:35

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:31', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e58b831-24d9-46b5-bde4-13130bcb024c' User entered 'None (1)'	System	29 Aug 2020 07:42:35
	System	29 Aug 2020 07:42:35

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:34', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e58b831-24d9-46b5-bde4-13130bcb024c'	System	29 Aug 2020 07:42:35
User entered '29 Aug 2020 03:42'	System	29 Aug 2020 07:42:35

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '28 Aug 2020 21:05'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 2'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:54:49', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'dbab5403-cc1c-49a0-ae10-af5f496c9dbd' User entered 'None (1)'	System	29 Aug 2020 23:55:08
	System	29 Aug 2020 23:55:08

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:54:52', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'dbab5403-cc1c-49a0-ae10-af5f496c9dbd'	System	29 Aug 2020 23:55:08
User entered 'No (N)'	System	29 Aug 2020 23:55:08

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:54:56', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'dbab5403-cc1c-49a0-ae10-af5f496c9dbd'	System	29 Aug 2020 23:55:08
User entered 'No (N)'	System	29 Aug 2020 23:55:08

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:55:03', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'dbab5403-cc1c-49a0-ae10-af5f496c9dbd' User entered 'None (1)'	System	29 Aug 2020 23:55:08
	System	29 Aug 2020 23:55:08

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:55:06', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'dbab5403-cc1c-49a0-ae10-af5f496c9dbd' User entered '29 Aug 2020 19:55'	System	29 Aug 2020 23:55:08
	System	29 Aug 2020 23:55:08

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 3'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:27:42', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c71b8c17-32ad-470f-8d29-750974c580bd' User entered 'None (1)'	System	31 Aug 2020 00:29:48
	System	31 Aug 2020 00:29:48

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:27:46', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c71b8c17-32ad-470f-8d29-750974c580bd' User entered 'No (N)'	System	31 Aug 2020 00:29:48
	System	31 Aug 2020 00:29:48

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:27:49', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c71b8c17-32ad-470f-8d29-750974c580bd' User entered 'No (N)'	System	31 Aug 2020 00:29:48
	System	31 Aug 2020 00:29:48

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:27:54', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c71b8c17-32ad-470f-8d29-750974c580bd' User entered 'None (1)'	System	31 Aug 2020 00:29:48
	System	31 Aug 2020 00:29:48

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:27:59', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c71b8c17-32ad-470f-8d29-750974c580bd' User entered '30 Aug 2020 20:27'	System	31 Aug 2020 00:29:48
	System	31 Aug 2020 00:29:48

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 4'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:35:33', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '75d46837-211c-4d27-a7fb-f5dc487ddf68'	System	01 Sep 2020 00:35:57
User entered 'None (1)'	System	01 Sep 2020 00:35:57

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:35:37', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '75d46837-211c-4d27-a7fb-f5dc487ddf68' User entered 'No (N)'	System	01 Sep 2020 00:35:57
	System	01 Sep 2020 00:35:57

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:35:40', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '75d46837-211c-4d27-a7fb-f5dc487ddf68' User entered 'No (N)'	System	01 Sep 2020 00:35:57
	System	01 Sep 2020 00:35:57

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:35:45', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '75d46837-211c-4d27-a7fb-f5dc487ddf68'	System	01 Sep 2020 00:35:57
User entered 'None (1)'	System	01 Sep 2020 00:35:57

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:35:52', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '75d46837-211c-4d27-a7fb-f5dc487ddf68'	System	01 Sep 2020 00:35:57
User entered '31 Aug 2020 20:35'	System	01 Sep 2020 00:35:57

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 5'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:19:54', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '85ca1042-1442-4a2c-b5f5-f38d86a6b35d' User entered 'None (1)'	System	02 Sep 2020 00:20:12
	System	02 Sep 2020 00:20:12

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:19:58', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '85ca1042-1442-4a2c-b5f5-f38d86a6b35d' User entered 'No (N)'	System	02 Sep 2020 00:20:12
	System	02 Sep 2020 00:20:12

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:20:02', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '85ca1042-1442-4a2c-b5f5-f38d86a6b35d' User entered 'No (N)'	System	02 Sep 2020 00:20:12
	System	02 Sep 2020 00:20:12

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:20:06', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '85ca1042-1442-4a2c-b5f5-f38d86a6b35d' User entered 'None (1)'	System	02 Sep 2020 00:20:12
	System	02 Sep 2020 00:20:12

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:20:10', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '85ca1042-1442-4a2c-b5f5-f38d86a6b35d'	System	02 Sep 2020 00:20:12
User entered '01 Sep 2020 20:20'	System	02 Sep 2020 00:20:12

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 6'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:33:40', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '848ebfc7-d31b-47dc-9dc0-735db0359342'	System	02 Sep 2020 22:33:54
User entered 'None (1)'	System	02 Sep 2020 22:33:54

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:33:43', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '848ebfc7-d31b-47dc-9dc0-735db0359342' User entered 'No (N)'	System	02 Sep 2020 22:33:54
	System	02 Sep 2020 22:33:54

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:33:46', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '848ebfc7-d31b-47dc-9dc0-735db0359342' User entered 'No (N)'	System	02 Sep 2020 22:33:54
	System	02 Sep 2020 22:33:54

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:33:50', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '848ebfc7-d31b-47dc-9dc0-735db0359342' User entered 'None (1)'	System	02 Sep 2020 22:33:54
	System	02 Sep 2020 22:33:54

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:33:53', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '848ebfc7-d31b-47dc-9dc0-735db0359342' User entered '02 Sep 2020 18:33'	System	02 Sep 2020 22:33:54
	System	02 Sep 2020 22:33:54

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 7'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:05:54', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3a185f1a-c127-4df9-b175-acf1542f4a2e' User entered 'None (1)'	System	04 Sep 2020 01:06:08
	System	04 Sep 2020 01:06:08

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:05:57', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3a185f1a-c127-4df9-b175-acf1542f4a2e' User entered 'No (N)'	System	04 Sep 2020 01:06:08
	System	04 Sep 2020 01:06:08

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:05:59', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3a185f1a-c127-4df9-b175-acf1542f4a2e' User entered 'No (N)'	System	04 Sep 2020 01:06:08
	System	04 Sep 2020 01:06:08

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:06:02', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3a185f1a-c127-4df9-b175-acf1542f4a2e' User entered 'None (1)'	System	04 Sep 2020 01:06:08
	System	04 Sep 2020 01:06:08

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:06:05', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3a185f1a-c127-4df9-b175-acf1542f4a2e'	System	04 Sep 2020 01:06:08
User entered '03 Sep 2020 21:06'	System	04 Sep 2020 01:06:08

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:49', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c2b0b41f-1e12-45ce-b2b3-833c04eb4066'	System	28 Aug 2020 22:08:16
User entered 'None (0)'	System	28 Aug 2020 22:08:16

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:51', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c2b0b41f-1e12-45ce-b2b3-833c04eb4066'	System	28 Aug 2020 22:08:16
User entered 'None (0)'	System	28 Aug 2020 22:08:16

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:54', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c2b0b41f-1e12-45ce-b2b3-833c04eb4066'	System	28 Aug 2020 22:08:16
User entered 'None (0)'	System	28 Aug 2020 22:08:16

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:57', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c2b0b41f-1e12-45ce-b2b3-833c04eb4066'	System	28 Aug 2020 22:08:16
User entered 'None (0)'	System	28 Aug 2020 22:08:16

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:07:59', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c2b0b41f-1e12-45ce-b2b3-833c04eb4066'	System	28 Aug 2020 22:08:16
User entered 'None (0)'	System	28 Aug 2020 22:08:16

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:08:01', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c2b0b41f-1e12-45ce-b2b3-833c04eb4066'	System	28 Aug 2020 22:08:16
User entered 'None (0)'	System	28 Aug 2020 22:08:16

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:08:07', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c2b0b41f-1e12-45ce-b2b3-833c04eb4066'	System	28 Aug 2020 22:08:16
User entered 'No (N)'	System	28 Aug 2020 22:08:16

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-28T18:08:12', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c2b0b41f-1e12-45ce-b2b3-833c04eb4066'	System	28 Aug 2020 22:08:16
User entered '28 Aug 2020 18:08'	System	28 Aug 2020 22:08:16

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '28 Aug 2020 17:40'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '28 Aug 2020 20:10'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:38', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '09709cd6-76a9-4237-9d20-b257a006c1bc' User entered 'None (0)'	System	29 Aug 2020 07:43:01
	System	29 Aug 2020 07:43:01

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:40', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '09709cd6-76a9-4237-9d20-b257a006c1bc' User entered 'None (0)'	System	29 Aug 2020 07:43:01
	System	29 Aug 2020 07:43:01

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:43', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '09709cd6-76a9-4237-9d20-b257a006c1bc' User entered 'None (0)'	System	29 Aug 2020 07:43:01
	System	29 Aug 2020 07:43:01

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:46', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '09709cd6-76a9-4237-9d20-b257a006c1bc' User entered 'None (0)'	System	29 Aug 2020 07:43:01
	System	29 Aug 2020 07:43:01

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:49', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '09709cd6-76a9-4237-9d20-b257a006c1bc' User entered 'None (0)'	System	29 Aug 2020 07:43:01
	System	29 Aug 2020 07:43:01

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:52', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '09709cd6-76a9-4237-9d20-b257a006c1bc' User entered 'None (0)'	System	29 Aug 2020 07:43:01
	System	29 Aug 2020 07:43:01

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:56', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '09709cd6-76a9-4237-9d20-b257a006c1bc'	System	29 Aug 2020 07:43:01
User entered 'No (N)'	System	29 Aug 2020 07:43:01

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T03:42:59', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '09709cd6-76a9-4237-9d20-b257a006c1bc' User entered '29 Aug 2020 03:42'	System	29 Aug 2020 07:43:01
	System	29 Aug 2020 07:43:01

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '28 Aug 2020 21:05'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 2'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:55:18', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '885afef0-ebb5-47b7-a5bb-9dc2c3025db3'	System	29 Aug 2020 23:55:42
User entered 'None (0)'	System	29 Aug 2020 23:55:42

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:55:21', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '885afef0-ebb5-47b7-a5bb-9dc2c3025db3'	System	29 Aug 2020 23:55:42
User entered 'None (0)'	System	29 Aug 2020 23:55:42

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:55:24', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '885afef0-ebb5-47b7-a5bb-9dc2c3025db3' User entered 'None (0)'	System	29 Aug 2020 23:55:42
	System	29 Aug 2020 23:55:42

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:55:27', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '885afef0-ebb5-47b7-a5bb-9dc2c3025db3' User entered 'None (0)'	System	29 Aug 2020 23:55:42
	System	29 Aug 2020 23:55:42

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:55:30', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '885afef0-ebb5-47b7-a5bb-9dc2c3025db3' User entered 'None (0)'	System	29 Aug 2020 23:55:42
	System	29 Aug 2020 23:55:42

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:55:32', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '885afef0-ebb5-47b7-a5bb-9dc2c3025db3' User entered 'None (0)'	System	29 Aug 2020 23:55:42
	System	29 Aug 2020 23:55:42

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:55:37', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '885afef0-ebb5-47b7-a5bb-9dc2c3025db3'	System	29 Aug 2020 23:55:42
User entered 'No (N)'	System	29 Aug 2020 23:55:42

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-29T19:55:40', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '885afef0-ebb5-47b7-a5bb-9dc2c3025db3'	System	29 Aug 2020 23:55:42
User entered '29 Aug 2020 19:55'	System	29 Aug 2020 23:55:42

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 3'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:28:16', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5d37bee7-ccc7-4e18-ae41-0831a633aa17'	System	31 Aug 2020 00:29:50
User entered 'No interference with activity (1)'	System	31 Aug 2020 00:29:50

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:28:19', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5d37bee7-ccc7-4e18-ae41-0831a633aa17' User entered 'None (0)'	System	31 Aug 2020 00:29:50
	System	31 Aug 2020 00:29:50

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:28:23', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5d37bee7-ccc7-4e18-ae41-0831a633aa17' User entered 'None (0)'	System	31 Aug 2020 00:29:50
	System	31 Aug 2020 00:29:50

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:28:27', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5d37bee7-ccc7-4e18-ae41-0831a633aa17' User entered 'None (0)'	System	31 Aug 2020 00:29:50
	System	31 Aug 2020 00:29:50

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:28:30', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5d37bee7-ccc7-4e18-ae41-0831a633aa17' User entered 'None (0)'	System	31 Aug 2020 00:29:50
	System	31 Aug 2020 00:29:50

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:28:33', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5d37bee7-ccc7-4e18-ae41-0831a633aa17' User entered 'None (0)'	System	31 Aug 2020 00:29:50
	System	31 Aug 2020 00:29:50

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:28:38', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5d37bee7-ccc7-4e18-ae41-0831a633aa17' User entered 'No (N)'	System	31 Aug 2020 00:29:50
	System	31 Aug 2020 00:29:50

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-30T20:28:45', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '5d37bee7-ccc7-4e18-ae41-0831a633aa17' User entered '30 Aug 2020 20:28'	System	31 Aug 2020 00:29:50
	System	31 Aug 2020 00:29:50

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 4'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:35:56', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a616869f-2fd3-45cc-a86a-8a6c63d4b17e' User entered 'None (0)'	System	01 Sep 2020 00:36:21
	System	01 Sep 2020 00:36:21

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:35:59', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a616869f-2fd3-45cc-a86a-8a6c63d4b17e' User entered 'None (0)'	System	01 Sep 2020 00:36:21
	System	01 Sep 2020 00:36:21

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:36:01', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a616869f-2fd3-45cc-a86a-8a6c63d4b17e' User entered 'None (0)'	System	01 Sep 2020 00:36:21
	System	01 Sep 2020 00:36:21

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:36:04', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a616869f-2fd3-45cc-a86a-8a6c63d4b17e' User entered 'None (0)'	System	01 Sep 2020 00:36:21
	System	01 Sep 2020 00:36:21

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:36:07', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a616869f-2fd3-45cc-a86a-8a6c63d4b17e' User entered 'None (0)'	System	01 Sep 2020 00:36:21
	System	01 Sep 2020 00:36:21

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:36:09', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a616869f-2fd3-45cc-a86a-8a6c63d4b17e' User entered 'None (0)'	System	01 Sep 2020 00:36:21
	System	01 Sep 2020 00:36:21

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:36:15', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a616869f-2fd3-45cc-a86a-8a6c63d4b17e' User entered 'No (N)'	System	01 Sep 2020 00:36:21
	System	01 Sep 2020 00:36:21

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-08-31T20:36:18', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a616869f-2fd3-45cc-a86a-8a6c63d4b17e' User entered '31 Aug 2020 20:36'	System	01 Sep 2020 00:36:21
	System	01 Sep 2020 00:36:21

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 5'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:20:15', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e20e5cf-99cc-4f77-bfc8-6707ca115d2b' User entered 'None (0)'	System	02 Sep 2020 00:20:39
	System	02 Sep 2020 00:20:39

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:20:17', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e20e5cf-99cc-4f77-bfc8-6707ca115d2b' User entered 'None (0)'	System	02 Sep 2020 00:20:39
	System	02 Sep 2020 00:20:39

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:20:20', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e20e5cf-99cc-4f77-bfc8-6707ca115d2b' User entered 'None (0)'	System	02 Sep 2020 00:20:39
	System	02 Sep 2020 00:20:39

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:20:23', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e20e5cf-99cc-4f77-bfc8-6707ca115d2b' User entered 'None (0)'	System	02 Sep 2020 00:20:39
	System	02 Sep 2020 00:20:39

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:20:25', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e20e5cf-99cc-4f77-bfc8-6707ca115d2b' User entered 'None (0)'	System	02 Sep 2020 00:20:39
	System	02 Sep 2020 00:20:39

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:20:28', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e20e5cf-99cc-4f77-bfc8-6707ca115d2b' User entered 'None (0)'	System	02 Sep 2020 00:20:39
	System	02 Sep 2020 00:20:39

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:20:32', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e20e5cf-99cc-4f77-bfc8-6707ca115d2b' User entered 'No (N)'	System	02 Sep 2020 00:20:39
	System	02 Sep 2020 00:20:39

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-01T20:20:35', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3e20e5cf-99cc-4f77-bfc8-6707ca115d2b'	System	02 Sep 2020 00:20:39
User entered '01 Sep 2020 20:20'	System	02 Sep 2020 00:20:39

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 6'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:33:57', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4389bdc3-14cf-4fb6-b418-9e19a53440ce' User entered 'None (0)'	System	02 Sep 2020 22:34:19
	System	02 Sep 2020 22:34:19

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:34:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4389bdc3-14cf-4fb6-b418-9e19a53440ce' User entered 'None (0)'	System	02 Sep 2020 22:34:19
	System	02 Sep 2020 22:34:19

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:34:03', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4389bdc3-14cf-4fb6-b418-9e19a53440ce' User entered 'None (0)'	System	02 Sep 2020 22:34:19
	System	02 Sep 2020 22:34:19

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:34:07', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4389bdc3-14cf-4fb6-b418-9e19a53440ce' User entered 'None (0)'	System	02 Sep 2020 22:34:19
	System	02 Sep 2020 22:34:19

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:34:09', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4389bdc3-14cf-4fb6-b418-9e19a53440ce' User entered 'None (0)'	System	02 Sep 2020 22:34:19
	System	02 Sep 2020 22:34:19

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:34:12', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4389bdc3-14cf-4fb6-b418-9e19a53440ce' User entered 'None (0)'	System	02 Sep 2020 22:34:19
	System	02 Sep 2020 22:34:19

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:34:15', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4389bdc3-14cf-4fb6-b418-9e19a53440ce' User entered 'No (N)'	System	02 Sep 2020 22:34:19
	System	02 Sep 2020 22:34:19

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-02T18:34:18', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '4389bdc3-14cf-4fb6-b418-9e19a53440ce' User entered '02 Sep 2020 18:34'	System	02 Sep 2020 22:34:19
	System	02 Sep 2020 22:34:19

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	28 Aug 2020 22:06:03
User entered 'Day 7'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:06:08', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '35eab135-936d-4e10-808f-a53989453e5d' User entered 'None (0)'	System	04 Sep 2020 01:06:27
	System	04 Sep 2020 01:06:27

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:06:10', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '35eab135-936d-4e10-808f-a53989453e5d' User entered 'None (0)'	System	04 Sep 2020 01:06:27
	System	04 Sep 2020 01:06:27

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:06:12', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '35eab135-936d-4e10-808f-a53989453e5d' User entered 'None (0)'	System	04 Sep 2020 01:06:27
	System	04 Sep 2020 01:06:27

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:06:15', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '35eab135-936d-4e10-808f-a53989453e5d' User entered 'None (0)'	System	04 Sep 2020 01:06:27
	System	04 Sep 2020 01:06:27

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:06:17', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '35eab135-936d-4e10-808f-a53989453e5d' User entered 'None (0)'	System	04 Sep 2020 01:06:27
	System	04 Sep 2020 01:06:27

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:06:19', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '35eab135-936d-4e10-808f-a53989453e5d' User entered 'None (0)'	System	04 Sep 2020 01:06:27
	System	04 Sep 2020 01:06:27

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:06:22', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '35eab135-936d-4e10-808f-a53989453e5d' User entered 'No (N)'	System	04 Sep 2020 01:06:27
	System	04 Sep 2020 01:06:27

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-09-03T21:06:25', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '35eab135-936d-4e10-808f-a53989453e5d' User entered '03 Sep 2020 21:06'	System	04 Sep 2020 01:06:27
	System	04 Sep 2020 01:06:27

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 22:06:03

US3412059

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:39

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 22:06:03

US3412059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:34:20

US3412059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:34:20

US3412059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:34:20

US3412059

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:34:20

US3412059

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:24:40
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:34:26

US3412059

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'I'	System	04 Sep 2020 12:34:26

US3412059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:30:21

US3412059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '11 Sep 2020'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:30:21

US3412059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:30:21

US3412059

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:30:21

US3412059

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	11 Sep 2020 13:30:26

US3412059

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'I'	System	11 Sep 2020 13:30:26

US3412059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Mason Urban (b) (4)	18 Sep 2020 12:12:15

US3412059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '18 Sep 2020'	Mason Urban (b) (4)	18 Sep 2020 12:12:15

US3412059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	18 Sep 2020 12:12:15

US3412059

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Mason Urban (b) (4)	18 Sep 2020 12:12:15

US3412059

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Mason Urban (b) (4)	18 Sep 2020 12:12:19

US3412059

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'I'	System	18 Sep 2020 12:12:19

US3412059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	30 Sep 2020 15:20:12

US3412059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User closed query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	(b) (4) (b) (4), (b) (6)	05 Oct 2020 05:16:06
Query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.'	Jacob sekinger (b) (4)	30 Sep 2020 15:31:17
answered with 'due to subject's schedule, subject had to come 1 day out of window. ' (Site from System).	(b) (4)	
User opened query 'Visit 3 Date is < 25 or > 35 days after Visit 2 vaccination. Please reconcile or confirm dates.' (Site from System).	System	30 Sep 2020 15:20:12
User entered '21 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	30 Sep 2020 15:20:12

US3412059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[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 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Clinic (Clinic)'	Jacob sekinger (b) (4)	30 Sep 2020 15:20:12

US3412059

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'VISIT3'	System	30 Sep 2020 15:20:12

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'No (N)'	Jacob sekinger (b) (4)	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered empty.	System	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered empty.	System	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered empty.	System	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered empty.	System	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered empty.	Jacob sekinger (b) (4)	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered empty.	System	30 Sep 2020 15:32:09

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33

US3412059

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33

US3412059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	30 Sep 2020 15:32:22

US3412059

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:39

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '21 Sep 2020'	Jacob sekinger (b) (4)	30 Sep 2020 15:32:22

US3412059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	30 Sep 2020 15:32:40

US3412059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '21 Sep 2020'	Jacob sekinger (b) (4)	30 Sep 2020 15:32:40

US3412059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered '8:40'	Jacob sekinger (b) (4)	30 Sep 2020 15:32:40

US3412059

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered '21 Sep 2020 8:40'	System	30 Sep 2020 15:32:40

US3412059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:47:08
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	30 Sep 2020 15:32:52

US3412059

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered '1'	System	30 Sep 2020 15:32:52

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 64'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-01T08:42:56', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '1d1bdb97-2c74-4691-b518-5f46a6fac42e' User entered 'No (N)'	System	01 Oct 2020 15:43:14
	System	01 Oct 2020 15:43:14

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-01T08:43:03', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '1d1bdb97-2c74-4691-b518-5f46a6fac42e'	System	01 Oct 2020 15:43:14
User entered 'No (N)'	System	01 Oct 2020 15:43:14

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-01T08:43:11', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '1d1bdb97-2c74-4691-b518-5f46a6fac42e' User entered '01 Oct 2020 08:43:11'	System	01 Oct 2020 15:43:14
	System	01 Oct 2020 15:43:14

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '30 Sep 2020 00:01'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '04 Oct 2020 23:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 71'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-08T08:26:24', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd57f1545-fc10-49d8-9d9f-7f15765d73fe'	System	08 Oct 2020 15:26:40
User entered 'No (N)'	System	08 Oct 2020 15:26:40

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-08T08:26:29', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd57f1545-fc10-49d8-9d9f-7f15765d73fe'	System	08 Oct 2020 15:26:40
User entered 'No (N)'	System	08 Oct 2020 15:26:40

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-08T08:26:34', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd57f1545-fc10-49d8-9d9f-7f15765d73fe' User entered '08 Oct 2020 08:26:34'	System	08 Oct 2020 15:26:40
	System	08 Oct 2020 15:26:40

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '07 Oct 2020 00:01'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '11 Oct 2020 23:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 78'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-14T13:01:52', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ed5d2132-7d1c-4e87-817d-4d332593b06e'	System	14 Oct 2020 17:02:42
User entered 'No (N)'	System	14 Oct 2020 17:02:42

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-14T13:01:58', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ed5d2132-7d1c-4e87-817d-4d332593b06e'	System	14 Oct 2020 17:02:42
User entered 'No (N)'	System	14 Oct 2020 17:02:42

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-14T13:02:02', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ed5d2132-7d1c-4e87-817d-4d332593b06e' User entered '14 Oct 2020 13:02:02'	System	14 Oct 2020 17:02:42
	System	14 Oct 2020 17:02:42

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '14 Oct 2020 00:01'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '18 Oct 2020 23:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 92'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-29T13:15:54', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f2df30f8-61c5-45a0-a784-6982e5544fdc'	System	29 Oct 2020 17:16:11
User entered 'No (N)'	System	29 Oct 2020 17:16:11

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-29T13:16:01', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f2df30f8-61c5-45a0-a784-6982e5544fdc'	System	29 Oct 2020 17:16:11
User entered 'No (N)'	System	29 Oct 2020 17:16:11

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-10-29T13:16:09', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'f2df30f8-61c5-45a0-a784-6982e5544fdc' User entered '29 Oct 2020 13:16:09'	System	29 Oct 2020 17:16:11
	System	29 Oct 2020 17:16:11

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '28 Oct 2020 00:01'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '01 Nov 2020 23:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 99'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-04T09:36:57', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e4f66b70-9474-4870-8875-50b5b1fb393d' User entered 'No (N)'	System	04 Nov 2020 14:37:09
	System	04 Nov 2020 14:37:09

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-04T09:37:02', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e4f66b70-9474-4870-8875-50b5b1fb393d' User entered 'No (N)'	System	04 Nov 2020 14:37:09
	System	04 Nov 2020 14:37:09

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-04T09:37:08', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e4f66b70-9474-4870-8875-50b5b1fb393d' User entered '04 Nov 2020 09:37:08'	System	04 Nov 2020 14:37:09
	System	04 Nov 2020 14:37:09

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '04 Nov 2020 00:01'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '08 Nov 2020 23:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 106'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-11T18:27:17', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '9216d316-70a4-471e-9916-359d356e216e'	System	11 Nov 2020 23:27:44
User entered 'No (N)'	System	11 Nov 2020 23:27:44

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-11T18:27:24', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '9216d316-70a4-471e-9916-359d356e216e' User entered 'No (N)'	System	11 Nov 2020 23:27:44
	System	11 Nov 2020 23:27:44

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-11T18:27:41', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '9216d316-70a4-471e-9916-359d356e216e' User entered '11 Nov 2020 18:27:41'	System	11 Nov 2020 23:27:44
	System	11 Nov 2020 23:27:44

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '11 Nov 2020 00:01'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '15 Nov 2020 23:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered 'Day 113'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-18T12:17:19', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '25138147-8951-4e8e-81e2-13d28a83d8c9' User entered 'No (N)'	System	18 Nov 2020 17:17:34
	System	18 Nov 2020 17:17:34

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-18T12:17:26', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '25138147-8951-4e8e-81e2-13d28a83d8c9'	System	18 Nov 2020 17:17:34
User entered 'No (N)'	System	18 Nov 2020 17:17:34

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-18T12:17:31', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '25138147-8951-4e8e-81e2-13d28a83d8c9'	System	18 Nov 2020 17:17:34
User entered '18 Nov 2020 12:17:31'	System	18 Nov 2020 17:17:34

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '18 Nov 2020 00:01'	System	31 Jul 2020 14:11:37

US3412059

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:09
Data entry locked.	System	31 Jul 2020 14:11:37
User entered '22 Nov 2020 23:59'	System	31 Jul 2020 14:11:37

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-19T16:30:01', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c597286c-b9b9-4179-b4cf-53de37b22a56'	System	19 Nov 2020 21:30:22
User entered 'No (N)'	System	19 Nov 2020 21:30:22

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-19T16:30:08', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c597286c-b9b9-4179-b4cf-53de37b22a56'	System	19 Nov 2020 21:30:22
User entered 'No (N)'	System	19 Nov 2020 21:30:22

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-19T16:30:16', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c597286c-b9b9-4179-b4cf-53de37b22a56'	System	19 Nov 2020 21:30:22
User entered '19 Nov 2020 16:30:16'	System	19 Nov 2020 21:30:22

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '15 Nov 2020 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '19 Nov 2020 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-22T06:33:35', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd7f7f62a-688a-482c-96d1-9e26725214ce' User entered 'No (N)'	System	22 Nov 2020 11:33:49

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-22T06:33:42', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd7f7f62a-688a-482c-96d1-9e26725214ce' User entered 'No (N)'	System	22 Nov 2020 11:33:49

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-22T06:33:47', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd7f7f62a-688a-482c-96d1-9e26725214ce' User entered '22 Nov 2020 06:33:47'	System	22 Nov 2020 11:33:49
	System	22 Nov 2020 11:33:49

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-30T12:53:18', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '221087ed-1757-4be1-b65d-2c18ed7e33a3'	System	30 Nov 2020 17:53:43
User entered 'No (N)'	System	30 Nov 2020 17:53:43

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-30T12:53:32', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '221087ed-1757-4be1-b65d-2c18ed7e33a3'	System	30 Nov 2020 17:53:43
User entered 'No (N)'	System	30 Nov 2020 17:53:43

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-11-30T12:53:39', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '221087ed-1757-4be1-b65d-2c18ed7e33a3' User entered '30 Nov 2020 12:53:39'	System	30 Nov 2020 17:53:43
	System	30 Nov 2020 17:53:43

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-06T08:06:34', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a292c53f-4d10-437b-bff7-8dce7b3b5ac4'	System	06 Dec 2020 13:07:36
User entered 'Yes (Y)'	System	06 Dec 2020 13:07:36

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-06T08:06:51', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a292c53f-4d10-437b-bff7-8dce7b3b5ac4'	System	06 Dec 2020 13:07:36
User entered 'No (N)'	System	06 Dec 2020 13:07:36

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-06T08:06:59', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a292c53f-4d10-437b-bff7-8dce7b3b5ac4'	System	06 Dec 2020 13:07:36
User entered 'No (N)'	System	06 Dec 2020 13:07:36

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-06T08:07:09', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a292c53f-4d10-437b-bff7-8dce7b3b5ac4'	System	06 Dec 2020 13:07:36
User entered 'No (N)'	System	06 Dec 2020 13:07:36

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-06T08:07:33', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a292c53f-4d10-437b-bff7-8dce7b3b5ac4' User entered '06 Dec 2020 08:07:33'	System	06 Dec 2020 13:07:36
	System	06 Dec 2020 13:07:36

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-13T14:29:43', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3de0f040-3a5e-4d83-917b-a289ae606eae' User entered 'No (N)'	System	13 Dec 2020 19:30:02
	System	13 Dec 2020 19:30:02

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-13T14:29:52', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3de0f040-3a5e-4d83-917b-a289ae606eae' User entered 'No (N)'	System	13 Dec 2020 19:30:02
	System	13 Dec 2020 19:30:02

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-13T14:29:58', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '3de0f040-3a5e-4d83-917b-a289ae606eae' User entered '13 Dec 2020 14:29:58'	System	13 Dec 2020 19:30:02
	System	13 Dec 2020 19:30:02

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-20T09:08:20', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c02d8627-75d8-4723-a596-7b25a2c39656'	System	20 Dec 2020 17:08:40
User entered 'No (N)'	System	20 Dec 2020 17:08:40

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-20T09:08:30', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c02d8627-75d8-4723-a596-7b25a2c39656'	System	20 Dec 2020 17:08:40
User entered 'No (N)'	System	20 Dec 2020 17:08:40

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-20T09:08:35', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'c02d8627-75d8-4723-a596-7b25a2c39656'	System	20 Dec 2020 17:08:40
User entered '20 Dec 2020 09:08:35'	System	20 Dec 2020 17:08:40

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-27T09:24:06', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'b474972c-1b25-4435-8833-a15fb57a78f9' User entered 'No (N)'	System	27 Dec 2020 17:24:23
	System	27 Dec 2020 17:24:23

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-27T09:24:14', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'b474972c-1b25-4435-8833-a15fb57a78f9' User entered 'No (N)'	System	27 Dec 2020 17:24:23
	System	27 Dec 2020 17:24:23

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2020-12-27T09:24:19', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'b474972c-1b25-4435-8833-a15fb57a78f9' User entered '27 Dec 2020 09:24:19'	System	27 Dec 2020 17:24:23
	System	27 Dec 2020 17:24:23

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-03T08:25:06', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e12656c3-9582-455a-be40-12243fc56caa' User entered 'No (N)'	System	03 Jan 2021 16:25:26
	System	03 Jan 2021 16:25:26

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-03T08:25:14', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e12656c3-9582-455a-be40-12243fc56caa' User entered 'No (N)'	System	03 Jan 2021 16:25:26
	System	03 Jan 2021 16:25:26

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-03T08:25:21', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e12656c3-9582-455a-be40-12243fc56caa' User entered '03 Jan 2021 08:25:21'	System	03 Jan 2021 16:25:26
	System	03 Jan 2021 16:25:26

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-10T05:44:39', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a6a0b1d4-89c0-4c68-beff-93a825914284'	System	10 Jan 2021 10:45:10
User entered 'No (N)'	System	10 Jan 2021 10:45:10

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-10T05:44:59', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a6a0b1d4-89c0-4c68-beff-93a825914284'	System	10 Jan 2021 10:45:10
User entered 'No (N)'	System	10 Jan 2021 10:45:10

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-10T05:45:08', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'a6a0b1d4-89c0-4c68-beff-93a825914284' User entered '10 Jan 2021 05:45:08'	System	10 Jan 2021 10:45:10
	System	10 Jan 2021 10:45:10

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-17T09:02:37', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'deeb502e-52c6-4bb5-9866-f773b4b44990'	System	17 Jan 2021 14:03:27
User entered 'No (N)'	System	17 Jan 2021 14:03:27

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-17T09:03:16', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'deeb502e-52c6-4bb5-9866-f773b4b44990'	System	17 Jan 2021 14:03:27
User entered 'No (N)'	System	17 Jan 2021 14:03:27

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-17T09:03:23', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'deeb502e-52c6-4bb5-9866-f773b4b44990' User entered '17 Jan 2021 09:03:23'	System	17 Jan 2021 14:03:27

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-24T09:17:32', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '2ec433d2-f9c5-4e7e-90a8-33af8dafc13e' User entered 'No (N)'	System	24 Jan 2021 14:17:48
	System	24 Jan 2021 14:17:48

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-24T09:17:39', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '2ec433d2-f9c5-4e7e-90a8-33af8dafc13e' User entered 'No (N)'	System	24 Jan 2021 14:17:48
	System	24 Jan 2021 14:17:48

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-24T09:17:44', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '2ec433d2-f9c5-4e7e-90a8-33af8dafc13e' User entered '24 Jan 2021 09:17:44'	System	24 Jan 2021 14:17:48
	System	24 Jan 2021 14:17:48

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-31T05:30:06', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '912dd60c-5450-4050-9c67-784249a3cb74'	System	31 Jan 2021 10:30:35
User entered 'No (N)'	System	31 Jan 2021 10:30:35

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-31T05:30:22', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '912dd60c-5450-4050-9c67-784249a3cb74'	System	31 Jan 2021 10:30:35
User entered 'No (N)'	System	31 Jan 2021 10:30:35

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-01-31T05:30:32', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '912dd60c-5450-4050-9c67-784249a3cb74'	System	31 Jan 2021 10:30:35
User entered '31 Jan 2021 05:30:32'	System	31 Jan 2021 10:30:35

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-07T13:14:11', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e7886ec0-d2f5-40cd-b517-e93c5f08b5be' User entered 'No (N)'	System	07 Feb 2021 18:14:32
	System	07 Feb 2021 18:14:32

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-07T13:14:20', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e7886ec0-d2f5-40cd-b517-e93c5f08b5be' User entered 'No (N)'	System	07 Feb 2021 18:14:32

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-07T13:14:29', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e7886ec0-d2f5-40cd-b517-e93c5f08b5be' User entered '07 Feb 2021 13:14:29'	System	07 Feb 2021 18:14:32

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-14T05:34:25', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '41253098-de55-438d-871c-7a0b819bbbb9' User entered 'No (N)'	System	14 Feb 2021 10:34:43

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-14T05:34:35', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '41253098-de55-438d-871c-7a0b819bbbb9'	System	14 Feb 2021 10:34:43
User entered 'No (N)'	System	14 Feb 2021 10:34:43

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-14T05:34:40', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '41253098-de55-438d-871c-7a0b819bbbb9' User entered '14 Feb 2021 05:34:40'	System	14 Feb 2021 10:34:43
	System	14 Feb 2021 10:34:43

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-21T07:39:13', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '6d87d508-37a0-4aed-b7f9-84c1b6e69fce' User entered 'No (N)'	System	21 Feb 2021 12:39:30
	System	21 Feb 2021 12:39:30

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-21T07:39:20', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '6d87d508-37a0-4aed-b7f9-84c1b6e69fce' User entered 'No (N)'	System	21 Feb 2021 12:39:30
	System	21 Feb 2021 12:39:30

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-21T07:39:27', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '6d87d508-37a0-4aed-b7f9-84c1b6e69fce' User entered '21 Feb 2021 07:39:27'	System	21 Feb 2021 12:39:30
	System	21 Feb 2021 12:39:30

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-28T09:45:40-08:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '6688e45f-49ba-4602-a213-eaacb8fb0ae7' User entered 'No (N)'	System	28 Feb 2021 17:45:54
	System	28 Feb 2021 17:45:54

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-28T09:45:47-08:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '6688e45f-49ba-4602-a213-eaach8fb0ae7'	System	28 Feb 2021 17:45:54
User entered 'No (N)'	System	28 Feb 2021 17:45:54

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-28T09:45:52-08:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '6688e45f-49ba-4602-a213-eaacb8fb0ae7' User entered '28 Feb 2021 17:45:52'	System	28 Feb 2021 17:45:54
	System	28 Feb 2021 17:45:54

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-07T01:42:28-08:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd7e3ae99-cf1c-4f71-9765-94727c16855f' User entered 'Yes (Y)'	System	07 Mar 2021 22:58:03
	System	07 Mar 2021 22:58:03

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-07T01:42:35-08:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd7e3ae99-cf1c-4f71-9765-94727c16855f' User entered 'No (N)'	System	07 Mar 2021 22:58:03

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-07T01:42:42-08:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd7e3ae99-cf1c-4f71-9765-94727c16855f' User entered 'No (N)'	System	07 Mar 2021 22:58:03
	System	07 Mar 2021 22:58:03

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-07T01:43:01-08:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd7e3ae99-cf1c-4f71-9765-94727c16855f' User entered 'Yes (Y)'	System	07 Mar 2021 22:58:03
	System	07 Mar 2021 22:58:03

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Please 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)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-07T14:57:34-08:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd7e3ae99-cf1c-4f71-9765-94727c16855f'	System	07 Mar 2021 22:58:03
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Mar 2021 22:58:03

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-07T14:57:54-08:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'd7e3ae99-cf1c-4f71-9765-94727c16855f' User entered '07 Mar 2021 22:57:54'	System	07 Mar 2021 22:58:03
	System	07 Mar 2021 22:58:03

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-14T08:34:26-07:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '398a9f50-91d5-4e93-b156-d1ca24641393'	System	14 Mar 2021 15:34:40
User entered 'No (N)'	System	14 Mar 2021 15:34:40

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-14T08:34:33-07:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '398a9f50-91d5-4e93-b156-d1ca24641393'	System	14 Mar 2021 15:34:40
User entered 'No (N)'	System	14 Mar 2021 15:34:40

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-14T08:34:38-07:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '398a9f50-91d5-4e93-b156-d1ca24641393'	System	14 Mar 2021 15:34:40
User entered '14 Mar 2021 08:34:38'	System	14 Mar 2021 15:34:40

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-21T08:47:08-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '67ddee6c-94cb-40ee-ac1f-d0fbd9276897'	System	21 Mar 2021 12:47:26
User entered 'No (N)'	System	21 Mar 2021 12:47:26

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-21T08:47:18-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '67ddee6c-94cb-40ee-ac1f-d0fbd9276897'	System	21 Mar 2021 12:47:26
User entered 'No (N)'	System	21 Mar 2021 12:47:26

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-21T08:47:23-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '67ddee6c-94cb-40ee-ac1f-d0fbd9276897'	System	21 Mar 2021 12:47:26
User entered '21 Mar 2021 08:47:23'	System	21 Mar 2021 12:47:26

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-28T08:52:26-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '0b7511ab-e2f5-4806-879e-5eb77014e067'	System	28 Mar 2021 12:52:44
User entered 'No (N)'	System	28 Mar 2021 12:52:44

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-28T08:52:34-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '0b7511ab-e2f5-4806-879e-5eb77014e067'	System	28 Mar 2021 12:52:44
User entered 'No (N)'	System	28 Mar 2021 12:52:44

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-03-28T08:52:41-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '0b7511ab-e2f5-4806-879e-5eb77014e067' User entered '28 Mar 2021 08:52:41'	System	28 Mar 2021 12:52:44
	System	28 Mar 2021 12:52:44

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-04T06:43:22-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cdbf8cf9-7275-496a-8fa0-4fae257ee3d5'	System	04 Apr 2021 10:43:33
User entered 'No (N)'	System	04 Apr 2021 10:43:33

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-04T06:43:26-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cdbf8cf9-7275-496a-8fa0-4fae257ee3d5'	System	04 Apr 2021 10:43:33
User entered 'No (N)'	System	04 Apr 2021 10:43:33

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-04T06:43:31-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cdbf8cf9-7275-496a-8fa0-4fae257ee3d5'	System	04 Apr 2021 10:43:33
User entered '04 Apr 2021 06:43:31'	System	04 Apr 2021 10:43:33

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-11T08:20:03-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '95e1eed2-c6dc-4579-a8ce-4e75d476ad59'	System	11 Apr 2021 12:20:19
User entered 'No (N)'	System	11 Apr 2021 12:20:19

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-11T08:20:10-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '95e1eed2-c6dc-4579-a8ce-4e75d476ad59'	System	11 Apr 2021 12:20:19
User entered 'No (N)'	System	11 Apr 2021 12:20:19

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-11T08:20:16-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '95e1eed2-c6dc-4579-a8ce-4e75d476ad59'	System	11 Apr 2021 12:20:19
User entered '11 Apr 2021 08:20:16'	System	11 Apr 2021 12:20:19

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-18T09:10:07-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '33ef536c-11dc-4dff-828a-668beeb5fc77'	System	18 Apr 2021 13:10:22
User entered 'No (N)'	System	18 Apr 2021 13:10:22

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-18T09:10:13-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '33ef536c-11dc-4dff-828a-668beeb5fc77'	System	18 Apr 2021 13:10:22
User entered 'No (N)'	System	18 Apr 2021 13:10:22

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-18T09:10:19-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: '33ef536c-11dc-4dff-828a-668beeb5fc77'	System	18 Apr 2021 13:10:22
User entered '18 Apr 2021 09:10:19'	System	18 Apr 2021 13:10:22

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-25T09:43:17-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ce52316a-795c-43a7-87f1-aab78b885ea1' User entered 'No (N)'	System	25 Apr 2021 13:43:26
	System	25 Apr 2021 13:43:26

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-25T09:43:20-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ce52316a-795c-43a7-87f1-aab78b885ea1' User entered 'No (N)'	System	25 Apr 2021 13:43:26

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-04-25T09:43:23-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'ce52316a-795c-43a7-87f1-aab78b885ea1' User entered '25 Apr 2021 09:43:23'	System	25 Apr 2021 13:43:26
	System	25 Apr 2021 13:43:26

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-05-02T06:12:55-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cee81afe-d3c8-4c84-a4b4-8417f9590d7f' User entered 'No (N)'	System	02 May 2021 10:13:08
	System	02 May 2021 10:13:08

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

Have you been exposed to someone with 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 (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-05-02T06:12:59-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cee81afe-d3c8-4c84-a4b4-8417f9590d7f' User entered 'No (N)'	System	02 May 2021 10:13:08
	System	02 May 2021 10:13:08

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-05-02T06:13:04-04:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'cee81afe-d3c8-4c84-a4b4-8417f9590d7f' User entered '02 May 2021 06:13:04'	System	02 May 2021 10:13:08
	System	02 May 2021 10:13:08

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 10:50:09

US3412059

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:39

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:50:09
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 10:50:09

US3412059

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:29:39

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:36:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-27T17:58:41-08:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e5d82dc5-e9ae-4a1f-9821-aa9cb2d8a09f' User entered 'No (N)'	System	28 Feb 2021 01:58:56
	System	28 Feb 2021 01:58:56

US3412059

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:29:39

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:36:51
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6FAD4B5A-6AD7-4FAC-BE8D-33A31BB76FD6)', Time: '2021-02-27T17:58:52-08:00', User OID: 'PatientReportedOutcome (US3412059)', ODM File OID: 'e5d82dc5-e9ae-4a1f-9821-aa9cb2d8a09f' User entered '28 Feb 2021 01:58:52'	System	28 Feb 2021 01:58:56
	System	28 Feb 2021 01:58:56

US3412059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'No (N)'	Steven Anderson (b) (4)	31 Mar 2021 18:03:52

US3412059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 18:03:52

US3412059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 18:03:52

US3412059

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'site inadvertently missed this call because not scheduling it in the CTMS' reason for change: Data Entry Error	Steven Anderson (b) (4)	31 Mar 2021 18:04:15
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 18:03:52

US3412059

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:30
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Dec 2020 14:03:27

US3412059

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 04:56:33
User entered 'I'	System	06 Dec 2020 14:03:27

US3412059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 14:03:49

US3412059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '28 Nov 2020'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 14:03:49

US3412059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 14:03:49

US3412059

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Melissa Fuson (b) (4)	06 Dec 2020 14:03:49

US3412059

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 14:03:57

US3412059

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User entered 'I'	System	06 Dec 2020 14:03:57

US3412059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Dec 2020 19:38:44

US3412059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '28 Dec 2020'	Mason Urban (b) (4)	28 Dec 2020 19:38:44

US3412059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	28 Dec 2020 19:38:44

US3412059

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Mason Urban (b) (4)	28 Dec 2020 19:38:44

US3412059

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Dec 2020 19:38:55

US3412059

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User entered 'I'	System	28 Dec 2020 19:38:55

US3412059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Jan 2021 21:05:14

US3412059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '25 Jan 2021'	Mason Urban (b) (4)	25 Jan 2021 21:05:14

US3412059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	25 Jan 2021 21:05:14

US3412059

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Mason Urban (b) (4)	25 Jan 2021 21:05:14

US3412059

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Jan 2021 21:05:19

US3412059

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 06:19:31
User entered 'I'	System	25 Jan 2021 21:05:19

US3412059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	(b) (4) Mylene Asmar-Rios	22 Feb 2021 16:11:11

US3412059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '22 Feb 2021'	(b) (4) Mylene Asmar-Rios	22 Feb 2021 16:11:11
	(b) (4)	

US3412059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Clinic (Clinic)'	Mylene Asmar-Rios (b) (4)	22 Feb 2021 16:11:11

US3412059

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User entered 'VISIT4'	System	22 Feb 2021 16:11:11

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'No (N)'	Andrea Newlands (b) (4)	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User entered empty.	System	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User entered empty.	System	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User entered empty.	System	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User entered empty.	System	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User entered empty.	System	30 Mar 2021 12:58:54

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19

US3412059

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:39

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19

US3412059

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:39

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	22 Feb 2021 16:11:18
	(b) (4)	

US3412059

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:39

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	(b) (4) Mylene Asmar-Rios	22 Feb 2021 16:11:18

US3412059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	02 Mar 2021 17:21:33

US3412059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '22 Feb 2021'	Andrea Newlands (b) (4)	02 Mar 2021 17:21:33

US3412059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '09:40'	Andrea Newlands (b) (4)	02 Mar 2021 17:21:33

US3412059

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User entered '22 Feb 2021 09:40'	System	02 Mar 2021 17:21:33

US3412059

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Feb 2021 16:11:23

US3412059

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 13:57:19
User entered 'I'	System	22 Feb 2021 16:11:23

US3412059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Mar 2021 15:05:00

US3412059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '23 Mar 2021'	Mason Urban (b) (4)	23 Mar 2021 15:05:00

US3412059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	23 Mar 2021 15:05:00

US3412059

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:39

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered empty.	Mason Urban (b) (4)	23 Mar 2021 15:05:00

US3412059

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Mar 2021 15:05:06

US3412059

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:39

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User entered 'I'	System	23 Mar 2021 15:05:06

US3412059

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

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	19 Jan 2021 19:31:05

US3412059

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

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '18 Jan 2021'	(b) (4) Mason Urban (b) (4)	19 Jan 2021 19:31:05

US3412059

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

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Clinic (Clinic)'	Mason Urban (b) (4)	19 Jan 2021 19:31:05

US3412059

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

Form: Visit Date

Generated On: 09 Jun 2021 17:29:39

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User entered 'UNBLND_DECIDE'	System	19 Jan 2021 19:31:05

US3412059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:39

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '18 Jan 2021'	(b) (4) Mason Urban (b) (4)	19 Jan 2021 19:31:24

US3412059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:39

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:57:26

US3412059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:39

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	19 Jan 2021 19:31:24

US3412059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:39

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:57:26

US3412059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:39

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '18 Jan 2021'	Mason Urban (b) (4)	19 Jan 2021 19:31:24

US3412059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:39

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	19 Jan 2021 19:31:24

US3412059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:39

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:10:14
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	19 Jan 2021 19:31:24
	(b) (4)	

US3412059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:39

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:10:14
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	19 Jan 2021 19:31:24
	(b) (4)	

US3412059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:39

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'No (N)'	Mason Urban (b) (4)	19 Jan 2021 19:31:24

US3412059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:39

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User entered empty.	System	19 Jan 2021 19:31:24

US3412059

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:39

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User entered empty.	System	19 Jan 2021 19:31:24

US3412059

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	19 Jan 2021 19:31:52

US3412059

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '18 Jan 2021'	Mason Urban (b) (4)	19 Jan 2021 19:31:52

US3412059

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '8:58'	(b) (4) Mason Urban (b) (4)	19 Jan 2021 19:31:52

US3412059

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User entered '18 Jan 2021 8:58'	System	19 Jan 2021 19:31:52

US3412059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:29:39

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'Yes (Y)'	Mason Urban (b) (4)	19 Jan 2021 19:32:16

US3412059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '18 Jan 2021'	Mason Urban (b) (4)	19 Jan 2021 19:32:16

US3412059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '9:13'	Mason Urban (b) (4)	19 Jan 2021 19:32:16

US3412059

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:13:17
User entered '18 Jan 2021 9:13'	System	19 Jan 2021 19:32:16

US3412059

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:29:39

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:25
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 16:11:31
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	08 Feb 2021 15:23:19
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:37:37
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User closed query 'Per DM CLR: Please confirm the AE term "WORSENING OF RIGHT LOWER EXTREMITY VASCULAR INSUFFICIENCY", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 06:08:13
Query 'Per DM CLR: Please confirm the AE term "WORSENING OF RIGHT LOWER EXTREMITY VASCULAR INSUFFICIENCY", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' answered with 'this has been addressed. it was considered past medical history and has been added into PMH section of edc.' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Mar 2021 19:27:33
User opened query 'Per DM CLR: Please confirm the AE term "WORSENING OF RIGHT LOWER EXTREMITY VASCULAR INSUFFICIENCY", as there is no associated baseline Med History condition. Clarify if this condition is an exacerbation of a baseline condition. If so, please add the corresponding condition to the Med History eCRF. Otherwise, consider deleting the term "worsening" from this event. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:57:57
User coded data point as SOC: Vascular disorders, HLGT: Arteriosclerosis, stenosis, vascular insufficiency and necrosis, HLT: Non-site specific necrosis and vascular insufficiency NEC, PT: Vascular insufficiency, LLT: Vascular insufficiency - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 15:42:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 15:42:58
Data point term sent to Coder	System	22 Feb 2021 16:19:54

PRODUCTION RELEASE (v12.003
EAB) (1725)

1671 of 2537

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'worsening of right lower extremity vascular insufficiency'	Mylene Asmar-Rios (b) (4)	22 Feb 2021 16:19:38

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered '11 Feb 2021'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 16:19:38

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	22 Feb 2021 16:19:38

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered 'Grade 1/Mild (Grade 1/Mild)'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Hospital Discharge Date \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered 'Related (RELATED)'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	22 Feb 2021 16:21:45
	(b) (4)	
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Feb 2021 16:20:22
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System).	System	22 Feb 2021 16:19:38
User entered '0'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios	22 Feb 2021 16:21:45
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	22 Feb 2021 16:20:22
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User closed query 'Per CDM: Per sponsor review, subject has not been lost to follow up, however outcome is reported as unknown. Please review and reconcile. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:05:32
Query 'Per CDM: Per sponsor review, subject has not been lost to follow up, however outcome is reported as unknown. Please review and reconcile. ' answered with 'this has been updated to not recovered/resolved. subject has reported that this has not fully resolved' (Site from DM).	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 17:12:12
Signature has been broken.	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 17:11:34
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 17:11:34
User opened query 'Per CDM: Per sponsor review, subject has not been lost to follow up, however outcome is reported as unknown. Please review and reconcile. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 17:06:05
User signature succeeded.	Richard Powell (b) (4) (b) (4)	15 Mar 2021 15:27:24
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 16:20:22
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Feb 2021 16:20:22
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Feb 2021 16:20:22
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Feb 2021 16:19:38
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Feb 2021 16:19:38

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[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 15:27:24
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	22 Feb 2021 16:19:38
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User closed query 'Per DM CLR: Narrative = DUPLEX SCAN VENOUS STUDY 11 FEB 2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Mar 2021 06:08:43
Query 'Per DM CLR: Narrative = DUPLEX SCAN VENOUS STUDY 11 FEB 2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'duplex scan has been added to con procedures list per query ' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Mar 2021 19:28:55
User opened query 'Per DM CLR: Narrative = DUPLEX SCAN VENOUS STUDY 11 FEB 2021. However, this is not recorded in the ConProc eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:57:51
User entered 'Subject states to have increased edema right lower extremity. Duplex scan venous study 11 Feb 2021, ongoing, vascular surgical consultation pending. Duplex scan report reviewed by investigator on subject mobile device confirms right lower extremity venous reflux.'	Mylene Asmar-Rios (b) (4)	22 Feb 2021 16:19:38

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	22 Feb 2021 16:19:38

US3412059

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Feb 2021 16:19:38

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:36:00
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	09 Mar 2021 16:17:59
User entered 'USA-US061-2021-mRNA-1273-P301000014'	System	09 Mar 2021 16:17:55
User entered 'New'	(b) (4), (b) (6)	09 Mar 2021 16:17:55

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'Per AE log: acute systolic failure, ischemic cardiomyopathy and precordial chest pain - please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:14:20
Query 'Per AE log: acute systolic failure, ischemic cardiomyopathy and precordial chest pain - please review and update accordingly' answered with 'those ae's listed have been added' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 19:01:15
User opened query 'Per AE log: acute systolic failure, ischemic cardiomyopathy and precordial chest pain - please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:25:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:36:02
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Acute myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4)	08 Mar 2021 20:19:50
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	08 Mar 2021 20:19:50
Data point term sent to Coder	System	08 Mar 2021 20:18:34
User entered 'acute myocardial infarction' reason for change: Data Entry Error	Andrea Newlands (b) (4)	08 Mar 2021 20:18:19
Data point term sent to Coder	System	08 Mar 2021 19:19:02
User entered 'AMI'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:36:07
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:36:09
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'No (N)'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:36:18
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'No (N)'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:41:38
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered '6 Mar 2021'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:21:23
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered empty.	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:21:25
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'No (N)'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
User closed query 'stop date = 06 Mar 2021 per source? Please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:34:12
DataPoint Verified.	(b) (4)	21 Apr 2021 19:33:02
Query 'stop date = 06 Mar 2021 per source? Please review and update accordingly' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 19:02:09
Signature has been broken.	Steven Anderson (b) (4)	21 Apr 2021 19:02:01
User entered '06 Mar 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 19:02:01
User opened query 'stop date = 06 Mar 2021 per source? Please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:46:19
User closed query 'PV Query: Please clarify end date as it should be when all symptoms resolved' (Site from Safety).	(b) (4)	23 Mar 2021 15:07:28
Query 'PV Query: Please clarify end date as it should be when all symptoms resolved' answered with 'pt report on 08mar2021 indicates he is back to baseline - date is correct' (Site from Safety).	Andrea Newlands (b) (4)	22 Mar 2021 12:31:10
User opened query 'PV Query: Please clarify end date as it should be when all symptoms resolved' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 15:13:00
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered '8 Mar 2021'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:46:24
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered empty.	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:46:26
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:46:28
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'Yes (Y)'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:46:30
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered '0'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:46:32
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'I'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:46:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	22 Mar 2021 12:32:17
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	22 Mar 2021 12:32:17
User entered '1' reason for change: Data Entry Error	Andrea Newlands (b) (4)	22 Mar 2021 12:32:17
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	22 Mar 2021 12:31:58
Signature has been broken.	System	22 Mar 2021 12:31:58
User entered '0' reason for change: Data Entry Error	Andrea Newlands (b) (4)	22 Mar 2021 12:31:58
User signature succeeded.	(b) (4)	15 Mar 2021 15:27:24
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	Richard Powell (b) (4)	08 Mar 2021 19:19:22
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	08 Mar 2021 19:19:22
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Mar 2021 19:19:22
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	08 Mar 2021 19:19:01
User entered '0'	System	08 Mar 2021 19:19:01
	Steven Anderson (b) (4)	08 Mar 2021 19:19:01
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:46:40
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered '06 Mar 2021' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	08 Mar 2021 20:18:35
User entered '6 Mar 2021'	(b) (4)	
	Steven Anderson (b) (4)	08 Mar 2021 19:19:01
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:46:46
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).		19 Apr 2021 01:25:24
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' answered with 'records have been faxed' (Site from Safety).	(b) (4), (b) (6)	15 Apr 2021 15:30:29
User entered '08 Mar 2021' reason for change: Data Entry Error		15 Apr 2021 15:30:00
User closed query 'PV Query: Please clarify hospital discharge date as narrative reports subject being discharged on 09 Mar 2021, but EDC reports 08 Mar 2021.' (Site from Safety).		23 Mar 2021 15:07:51
Query 'PV Query: Please clarify hospital discharge date as narrative reports subject being discharged on 09 Mar 2021, but EDC reports 08 Mar 2021.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	22 Mar 2021 12:30:03
Signature has been broken.	(b) (4)	Andrea Newlands (b) (4) 22 Mar 2021 12:29:53
User entered '09 Mar 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	22 Mar 2021 12:29:53
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 15:13:22

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'PV Query: Please clarify hospital discharge date as narrative reports subject being discharged on 09 Mar 2021, but EDC reports 08 Mar 2021.' (Site from Safety). User signature succeeded.	(b) (4), (b) (6) Richard Powell (b) (4)	18 Mar 2021 15:11:56 15 Mar 2021 15:27:24
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	08 Mar 2021 20:17:57
User entered '08 Mar 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	08 Mar 2021 20:17:57
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	08 Mar 2021 19:19:22
User entered '9 Mar 2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Mar 2021 19:19:22
User entered '8 Mar 2021'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:46:54
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
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).	(b) (4)	08 Mar 2021 19:19:42
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).	System	08 Mar 2021 19:19:42
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Mar 2021 19:19:42
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).	(b) (4)	08 Mar 2021 19:19:01
User entered 'Unknown (UNK)'	System	08 Mar 2021 19:19:01
	Steven Anderson (b) (4)	08 Mar 2021 19:19:01
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:46:56
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered empty.	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:46:58
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered '0'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:47:01
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered '0'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:47:04
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered '0'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:47:06
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:47:13
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:47:15
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	
	Steven Anderson (b) (4)	08 Mar 2021 19:19:01
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:34:30
Signature has been broken.	Steven Anderson (b) (4)	21 Apr 2021 19:02:01
User entered '0' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	21 Apr 2021 19:02:01
User signature succeeded.	(b) (4) Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered '1'	(b) (4) Steven Anderson (b) (4)	08 Mar 2021 19:19:01
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
User closed query 'ConMeds given per hospital records - please consider checking box and updating ConMeds' (Site from CRA). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:35:54 21 Apr 2021 19:34:57
Query 'ConMeds given per hospital records - please consider checking box and updating ConMeds' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:02:18
Signature has been broken.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:02:01
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:02:01
User opened query 'ConMeds given per hospital records - please consider checking box and updating ConMeds' (Site from CRA). User closed query 'PV Query: Please clarify if con med, losartan 50 mg, is duplicated or if subject takes two doses.' (Site from Safety).	(b) (4), (b) (6)	21 Apr 2021 14:20:07 23 Mar 2021 15:08:00
Query 'PV Query: Please clarify if con med, losartan 50 mg, is duplicated or if subject takes two doses.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	22 Mar 2021 12:36:37
User opened query 'PV Query: Please clarify if con med, losartan 50 mg, is duplicated or if subject takes two doses.' (Site from Safety).	(b) (4), (b) (6)	18 Mar 2021 15:11:36
User signature succeeded.	Richard Powell (b) (4) (b) (4)	15 Mar 2021 15:27:24
User entered '0'	Steven Anderson (b) (4) (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
User closed query 'Cradiac catheterization per hospital records - please review and update accordingly - add to Con Proc CRF' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:38:43
DataPoint Verified.		21 Apr 2021 19:35:10
Query 'Cradiac catheterization per hospital records - please review and update accordingly - add to Con Proc CRF' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 19:02:24
Signature has been broken.	Steven Anderson (b) (4)	21 Apr 2021 19:02:01
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 19:02:01
User opened query 'Cradiac catheterization per hospital records - please review and update accordingly - add to Con Proc CRF' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 14:20:59
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered '0'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:21:05
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 14:21:07
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24
User entered empty.	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
User closed query ' PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?	(b) (4), (b) (6)	27 Apr 2021 14:05:28
' (Site from Safety). 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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).		27 Apr 2021 14:05:24
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' answered with 'records faxed on 15APR2021' (Site from Safety).		26 Apr 2021 20:01:07
Query ' PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?		26 Apr 2021 19:58:48
' answered with 'AE was ended on the same day the subject was discharged per medical records. ' (Site from Safety). User opened query ' PV Query: Please provide the reason why the subject remained hospitalized even after the event resolved. Did the subject experience another SAE?		23 Apr 2021 21:11:42
' (Site from Safety).		

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Narrative](#)

Audit	User	Time (GMT)
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 (add protocol and subject ID to cover page). Please leave query unanswered until records are sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	23 Apr 2021 21:11:35
User closed query 'please update narrative and send records to PV' (Site from CRA).		21 Apr 2021 19:41:08
User closed query 'Subject discharged on 08 Mar 2021 per records? Please confirm ad update' (Site from CRA).		21 Apr 2021 19:38:56
DataPoint Verified.		21 Apr 2021 19:35:34
Query 'please update narrative and send records to PV' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 19:09:28
Signature has been broken.	Steven Anderson (b) (4)	21 Apr 2021 19:09:16

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SITE FOLLOWED UP WITH E-DIARY REPORT ON 08-MAR-2021 AND WAS NOTIFIED OF THE SUBJECT BEEING SEEN AT AN ER ON 06-MAR-2021 FOR AN AMI. PER SUBJECT AN IMMEDIATE HEART CATH WAS PERFORMED. 98% BLOCKAGE IN LAD CORONARY ARTERY WAS IDENTIFIED AND A STENT WAS SUCCESSFULLY PLACED. LATER THAT SAME DAY HE STATES HE DEVELOPED CHEST PAIN AGAIN. A SECOND HEART CATH WAS PERFORMED, BUT THE PHYSICIAN FELT ALL WAS STABLE AND NO BLOCKAGES NEEDED ADDRESSED. HIS IS TO BE DISCHARGED 09-MAR-2021. HE PLANS TO STAY IN OREGON UNTIL 11-MAR-2021. HE STATES THAT HE IS FEELING MUCH BETTER AND IS BACK TO BASELINE. Subject presented to ED as a 69 y/o male with history of hyperlipidemia, HTN, and vascular insufficiency, and sudden onset severe chest pain on 06-mar-2021. Received blinded mrna-1273 on 03-jul-20 and 28-aug-20. Initial presentation diaphoretic, ill appearing, and stable vitals signs sa02 93%. Physical exam with in normal limits. Labs: CBL/ BMP wnl, troponin t 3.34 06-mar-21, 1.54 07-mar-21, exg st elevation 06-mar-21, covid test negative. imaging: TTE 06-mar-21, coronary angiograph with stent placement LAD. Subject responded well to PCI procedure then presented with chest pain same day and coronary angiograph was repeated. subject improved and was discharged on 08-mar-2021' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 19:09:16
Query 'Subject discharged on 08 Mar 2021 per records? Please confirm ad update' answered with 'this is correct and has been updated' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 19:02:34
User opened query 'please update narrative and send records to PV' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 13:53:11
User opened query 'Subject discharged on 08 Mar 2021 per records? Please confirm ad update' (Site from CRA).		21 Apr 2021 13:52:41

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).	(b) (4), (b) (6)	19 Apr 2021 01:25:43
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).		19 Apr 2021 01:25:39
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 'updated' (Site from Safety).		15 Apr 2021 16:16:55
Query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' answered with 'results were negative' (Site from Safety).		15 Apr 2021 15:31:17
User closed query 'Per DM CLR: Narrative indicates that subject had " HEART CATH, STENT, & SECOND HEART CATH." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).		13 Apr 2021 12:06:10

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Narrative indicates that subject had " HEART CATH, STENT, & SECOND HEART CATH." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' answered with 'site is still awaiting medical records from where subject was seen. subject was seen out of state so site is trying to obtain all information possible before updating' (Site from DM).	Steven Anderson (b) (4)	12 Apr 2021 17:17:23
User opened query 'Per DM CLR: Narrative indicates that subject had " HEART CATH, STENT, & SECOND HEART CATH." However, this information is not recorded in the appropriate eCRF pages. Please review and ensure that these are captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:43:02
User opened query 'PV Query: Please provide the results of any COVID-19 testing performed during hospital admission, including date of collection and type of testing.? If not done, please state so.' (Site from Safety).		18 Mar 2021 15:12:29
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).		18 Mar 2021 15:12:13
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:27:24

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Site followed up with e-diary report on 08-mar-2021 and was notified of the subject beeing seen at an ER on 06-mar-2021 for an AMI. Per subject an immediate heart cath was performed. 98% blockage in LAD coronary artery was identified and a stent was successfully placed. Later that same day he states he developed chest pain again. a second heart cath was performed, but the physician felt all was stable and no blockages needed addressed. His is to be discharged 09-mar-2021. He plans to stay in Oregon until 11-mar-2021. he states that he is feeling much better and is back to baseline. Site will request medical records.'	Steven Anderson (b) (4)	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	08 Mar 2021 19:19:01

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	30 Apr 2021 14:14:32
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:36:58
Reviewed for Safety.		29 Apr 2021 21:08:00
User entered 'USA-US061-2021-mRNA-1273-P301000014'		29 Apr 2021 21:07:16

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
	(b) (4)	
User coded data point as SOC: Cardiac disorders, HLGT: Heart failures, HLT: Left ventricular failures, PT: Acute left ventricular failure, LLT: Acute systolic heart failure - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:14:54
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 06:14:54
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:47
Data point term sent to Coder	System	21 Apr 2021 18:53:11
User entered 'Acute systolic Failure'	Steven Anderson (b) (4)	21 Apr 2021 18:52:40
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered '08 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:35:59
User closed query 'Per CDM re-query: Response states that the patient was hospitalised however 'Requires inpatient or prolongation of existing Hospitalization' is blank. Please review and update as appropriate.' (Site from DM).		29 Apr 2021 08:18:09
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
Query 'Per CDM re-query: Response states that the patient was hospitalised however 'Requires inpatient or prolongation of existing Hospitalization' is blank. Please review and update as appropriate.' answered with 'information has been updated' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 13:20:12
DataPoint Un-verified.		28 Apr 2021 13:19:46
User entered 'Yes (Y)' reason for change: Data Entry Error		28 Apr 2021 13:19:46
User opened query 'Per CDM re-query: Response states that the patient was hospitalised however 'Requires inpatient or prolongation of existing Hospitalization' is blank. Please review and update as appropriate.' (Site from DM).		27 Apr 2021 08:36:42
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		27 Apr 2021 08:35:35
DataPoint Verified.		21 Apr 2021 20:16:47
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'Acute MI is the sae however due to subject being hospitalized this was listed as a grade 4' (Site from System).	Steven Anderson (b) (4)	21 Apr 2021 19:03:50
User opened query 'AE severity is Grade 4, but is the System adverse event serious is No. Please confirm or correct.' (Site from System).		21 Apr 2021 18:52:40
User entered 'No (N)'	Steven Anderson (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered '0'	Steven Anderson (b) (4)	21 Apr 2021 18:52:40
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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). User signature succeeded.	(b) (4), (b) (6)	29 Apr 2021 08:17:54
DataPoint Verified.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
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 'information is not missing' (Site from System).	(b) (4), (b) (6)	28 Apr 2021 13:29:44
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	28 Apr 2021 13:19:46
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 13:19:46
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 13:19:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered '0'	Steven Anderson (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4)	28 Apr 2021 13:29:46
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 13:19:46
User entered '06 Mar 2021' reason for change: Data Entry Error		28 Apr 2021 13:19:46
DataPoint Verified.		21 Apr 2021 20:16:47
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:52:40
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4)	28 Apr 2021 13:29:48
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 13:19:46
User entered '08 Mar 2021' reason for change: Data Entry Error		28 Apr 2021 13:19:46
DataPoint Verified.		21 Apr 2021 20:16:47
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:52:40
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Please provide response for this field in the data field of EDC. Thank you. ' (Site from DM).	(b) (4), (b) (6)	01 May 2021 08:32:21
User signature succeeded.	Richard Powell (b) (4)	30 Apr 2021 14:14:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	30 Apr 2021 12:36:05
Query 'Per CDM re-query: Please provide response for this field in the data field of EDC. Thank you. ' answered with 'information has been updated' (Site from DM).		30 Apr 2021 12:13:07
DataPoint Un-verified.		30 Apr 2021 12:12:36
Signature has been broken.		30 Apr 2021 12:12:36
User entered 'No (N)' reason for change: Data Entry Error		30 Apr 2021 12:12:36
User opened query 'Per CDM re-query: Please provide response for this field in the data field of EDC. Thank you. ' (Site from DM).		29 Apr 2021 08:17:51
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:52:40
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered 'I'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:16:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 13:19:46
User entered '0'	System	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 18:52:40

US3412059

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:29:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 12:12:36

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	30 Apr 2021 14:14:32
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:36:30
User entered 'USA-US061-2021-mRNA-1273-P301000014'		29 Apr 2021 21:08:34

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User coded data point as SOC: Cardiac disorders, HLGT: Myocardial disorders, HLT: Cardiomyopathies, PT: Ischaemic cardiomyopathy, LLT: Ischemic cardiomyopathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:00:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:00:36
Data point term sent to Coder	System	21 Apr 2021 18:54:16
User entered 'Ischemic Cardiomyopathy'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Response states that the patient was hospitalised however 'Requires inpatient or prolongation of existing Hospitalization' is blank. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	29 Apr 2021 08:18:44
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 13:30:32
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Apr 2021 13:22:08
Query 'Per CDM re-query: Response states that the patient was hospitalised however 'Requires inpatient or prolongation of existing Hospitalization' is blank. Please review and update as appropriate.' answered with 'information has been updated' (Site from DM).	(b) (4), (b) (6)	28 Apr 2021 13:21:47
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	28 Apr 2021 13:21:28
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 13:21:28
User entered 'Yes (Y)' reason for change: Data Entry Error		28 Apr 2021 13:21:28
User opened query 'Per CDM re-query: Response states that the patient was hospitalised however 'Requires inpatient or prolongation of existing Hospitalization' is blank. Please review and update as appropriate.' (Site from DM).		27 Apr 2021 08:37:00
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		27 Apr 2021 08:36:53
DataPoint Verified.		21 Apr 2021 20:17:03
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'Acute MI is the sae however due to subject being hospitalized this was listed as a grade 4' (Site from System).	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:03:59

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User opened query 'AE severity is Grade 4, but is the System adverse event serious is No. Please confirm or correct.' (Site from System).		21 Apr 2021 18:53:51
User entered 'No (N)'	Steven Anderson (b) (4)	21 Apr 2021 18:53:51
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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). User signature succeeded.	(b) (4), (b) (6)	29 Apr 2021 08:18:47
DataPoint Verified.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
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 'information is not missing' (Site from System).	(b) (4), (b) (6)	28 Apr 2021 13:30:39
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		28 Apr 2021 13:22:27
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		28 Apr 2021 13:22:08
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). DataPoint Un-verified.	System	28 Apr 2021 13:22:08
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	28 Apr 2021 13:22:08
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System). DataPoint Verified.	System	28 Apr 2021 13:21:28
	(b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered '0'	Steven Anderson (b) (4)	21 Apr 2021 18:53:51
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4)	28 Apr 2021 13:30:40
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 13:21:28
User entered '06 Mar 2021' reason for change: Data Entry Error		28 Apr 2021 13:21:28
DataPoint Verified.		21 Apr 2021 20:17:03
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:53:51
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 13:30:42
DataPoint Un-verified.		28 Apr 2021 13:21:28
User entered '08 Mar 2021' reason for change: Data Entry Error		28 Apr 2021 13:21:28
DataPoint Verified.		21 Apr 2021 20:17:03
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: A response is required for this field (either Yes or No). Please update accordingly. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	01 May 2021 08:32:27
DataPoint Verified.	Richard Powell (b) (4)	30 Apr 2021 14:14:32
Query 'Per CDM re-query: A response is required for this field (either Yes or No). Please update accordingly. ' answered with 'information has been updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 12:36:23
Signature has been broken.		30 Apr 2021 12:14:24
User entered 'No (N)' reason for change: Data Entry Error		30 Apr 2021 12:14:08
User opened query 'Per CDM re-query: A response is required for this field (either Yes or No). Please update accordingly. ' (Site from DM). User signature succeeded.		30 Apr 2021 12:14:08
DataPoint Verified.		29 Apr 2021 08:20:10
	Richard Powell (b) (4)	28 Apr 2021 21:46:21
	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:53:51
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered 'I'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:03
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 13:21:28
User entered '0'	System	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 18:53:51

US3412059

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:29:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 12:14:08

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	30 Apr 2021 14:14:32
DataPoint Verified.	(b) (4), (b) (6)	30 Apr 2021 12:36:50
User entered 'USA-US061-2021-mRNA-1273-P301000014'		29 Apr 2021 21:09:06

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain precordial - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	22 Apr 2021 14:13:56
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 14:13:56
DataPoint Verified.	(b) (4)	22 Apr 2021 14:05:29
User closed query 'please correct spelling precordial chest pain' (Site from CRA).	(b) (4), (b) (6)	22 Apr 2021 14:05:10
Data point term sent to Coder	System	22 Apr 2021 12:48:44
Query 'please correct spelling precordial chest pain' answered with 'this has been corrected' (Site from CRA).	Steven Anderson (b) (4)	22 Apr 2021 12:48:19
Coding entries removed.	(b) (4)	
	Steven Anderson (b) (4)	22 Apr 2021 12:47:51
User entered 'PRECoRDIAL CHEST PAIN' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	22 Apr 2021 12:47:51
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Chest pain precordial - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 07:06:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Apr 2021 07:06:50
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:32
DataPoint Verified.		21 Apr 2021 20:17:26
User opened query 'please correct spelling precordial chest pain' (Site from CRA).		21 Apr 2021 19:15:52
Data point term sent to Coder	System	21 Apr 2021 18:55:17
User entered 'Precardial Chest Pain'	Steven Anderson (b) (4)	21 Apr 2021 18:54:52
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: Response states that the patient was hospitalised however 'Requires inpatient or prolongation of existing Hospitalization' is blank. Please review and update as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	29 Apr 2021 08:18:53
DataPoint Verified.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
Query 'Per CDM re-query: Response states that the patient was hospitalised however 'Requires inpatient or prolongation of existing Hospitalization' is blank. Please review and update as appropriate.' answered with 'information has been updated' (Site from DM). DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	28 Apr 2021 13:30:55
User entered 'Yes (Y)' reason for change: Data Entry Error		28 Apr 2021 13:23:54
User opened query 'Per CDM re-query: Response states that the patient was hospitalised however 'Requires inpatient or prolongation of existing Hospitalization' is blank. Please review and update as appropriate.' (Site from DM).		28 Apr 2021 13:23:21
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System). DataPoint Verified.		28 Apr 2021 13:23:21
		27 Apr 2021 08:37:22
		27 Apr 2021 08:37:14
	(b) (4), (b) (6)	21 Apr 2021 20:17:26
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'this was not indicated as the sae subjects acut MI was designated the ae and this was just a corresponding AE. However, due to the subject going to the hospital it was listed as a grade 4' (Site from System).	Steven Anderson (b) (4)	21 Apr 2021 18:59:55
User opened query 'AE severity is Grade 4, but is the System adverse event serious is No. Please confirm or correct.' (Site from System).	(b) (4)	21 Apr 2021 18:54:52
User entered 'No (N)'	Steven Anderson (b) (4)	21 Apr 2021 18:54:52
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
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)	29 Apr 2021 08:18:55
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4), (b) (6)	28 Apr 2021 13:31:05
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 'information is not missing' (Site from System).		28 Apr 2021 13:24:13
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	28 Apr 2021 13:23:21
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 13:23:21
User entered '1' reason for change: Data Entry Error		28 Apr 2021 13:23:21
DataPoint Verified.		21 Apr 2021 20:17:26
User entered '0'	Steven Anderson (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4)	28 Apr 2021 13:31:06
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 13:23:21
User entered '06 Mar 2021' reason for change: Data Entry Error		28 Apr 2021 13:23:21
DataPoint Verified.		21 Apr 2021 20:17:26
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:54:52
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4)	28 Apr 2021 13:31:08
DataPoint Un-verified.	(b) (4), (b) (6)	28 Apr 2021 13:23:21
User entered '08 Mar 2021' reason for change: Data Entry Error		28 Apr 2021 13:23:21
DataPoint Verified.		21 Apr 2021 20:17:26
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:54:52
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User closed query 'Per CDM re-query: A response is required for this field (either Yes or No). Please update accordingly. ' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	01 May 2021 08:32:33
DataPoint Verified.	Richard Powell (b) (4)	30 Apr 2021 14:14:32
Query 'Per CDM re-query: A response is required for this field (either Yes or No). Please update accordingly. ' answered with 'information has been updated' (Site from DM). DataPoint Un-verified.	(b) (4), (b) (6)	30 Apr 2021 12:36:43
Signature has been broken.		30 Apr 2021 12:15:18
User entered 'No (N)' reason for change: Data Entry Error		30 Apr 2021 12:15:02
User opened query 'Per CDM re-query: A response is required for this field (either Yes or No). Please update accordingly. ' (Site from DM). User signature succeeded.		30 Apr 2021 12:15:02
DataPoint Verified.		29 Apr 2021 08:20:27
	Richard Powell (b) (4)	28 Apr 2021 21:46:21
	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 18:54:52
	(b) (4)	

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered 'I'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	28 Apr 2021 21:46:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 20:17:26
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	28 Apr 2021 13:23:21
User entered '0'	System	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 18:54:52

US3412059

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:29:39

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	30 Apr 2021 12:15:02

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:25
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:22
User closed query 'Per CDM: Diary Dose 2 Temperature Day, Log Line #4 edairy reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:29:01
Query 'Per CDM: Diary Dose 2 Temperature Day, Log Line #4 edairy reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' answered with 'This medication as been added into EDC' (Site from DM).	Steven Anderson (b) (4) (b) (4)	19 Oct 2020 13:17:00
User opened query 'Per CDM: Diary Dose 2 Temperature Day, Log Line #4 edairy reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 04:16:59
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:20:34
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 20:28:11

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Aug 2020 15:29:28
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 Aug 2020 15:29:28
Data point term sent to Coder	System	19 Aug 2020 15:28:49
User entered 'AMLODIPINE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:28:19

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'HTN'	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered '10' reason for change: Data Entry Error	Andrea Newlands (b) (4)	02 Mar 2021 17:30:41
	(b) (4)	
User entered '5' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 19:49:00
	(b) (4)	
User entered '10' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Aug 2020 15:32:25
	(b) (4)	
User entered '5'	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'once daily (QD)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	02 Mar 2021 17:30:41
	(b) (4)	
User entered 'other (OTHER)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 19:49:00
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	02 Mar 2021 17:30:41
	(b) (4)	
User entered '2 PILLS ONCE A DAY' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 19:49:00
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:27:43
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	19 Aug 2020 15:28:19
User entered 'UN UNK 2018'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:28:19

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 15:28:19
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 17:30:41
User entered empty.	System	17 Nov 2020 19:49:00
User entered '1'	System	19 Aug 2020 15:28:19

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	02 Mar 2021 17:30:41
User entered empty.	System	17 Nov 2020 19:49:00
User entered '1'	System	19 Aug 2020 15:28:19

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	02 Mar 2021 17:30:41
User entered empty.	System	17 Nov 2020 19:49:00
User entered '804 (804)'	System	19 Aug 2020 15:28:19

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Aug 2020 15:33:31
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 Aug 2020 15:33:31
Data point term sent to Coder User entered 'LOSARTAN'	System Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:32:55 19 Aug 2020 15:31:56

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:31:56

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'HYPERTENSION'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:31:56

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '25'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:31:56

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'mg (mg)'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:31:56
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:31:56

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:31:56
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:31:56

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Oral (ORAL)'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:31:56
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:31:56
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:27:43
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	19 Aug 2020 15:31:56
User entered 'UN UNK 2018'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:31:56

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:31:56

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 16:22:18
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Aug 2020 15:31:56
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'un Sep 2020' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 16:22:18
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 15:31:56
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:31:56
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User entered '1'	System	19 Aug 2020 15:31:56

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User entered '1'	System	19 Aug 2020 15:31:56

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:23:37
User entered '804 (804)'	System	19 Aug 2020 15:31:56

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: OTHER ANTIFUNGALS FOR TOPICAL USE, PRODUCT: CICLOPIROX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 06:07:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	11 Dec 2020 06:07:45
Data point term sent to Coder	System	08 Dec 2020 16:28:02
Data point term sent to Coder	System	08 Dec 2020 16:23:44
Coding entries removed.	Melissa Fuson (b) (4)	08 Dec 2020 16:23:03
User entered 'CICLOPIROX (0.77%)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	08 Dec 2020 16:23:03
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: OTHER ANTIFUNGALS FOR TOPICAL USE, PRODUCT: CICLOPIROX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 21:43:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Nov 2020 21:43:54
Data point term sent to Coder	System	17 Nov 2020 19:54:24
Coding entries removed.	Melissa Fuson (b) (4)	17 Nov 2020 19:54:13
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIFUNGALS FOR DERMATOLOGICAL USE, ATC: ANTIFUNGALS FOR TOPICAL USE, ATC: OTHER ANTIFUNGALS FOR TOPICAL USE, PRODUCT: CICLOPIROX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 00:16:17

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'CICLOPIROX'	Coder Import (b) (4) (b) (4) System Mylene Asmar-Rios (b) (4)	20 Aug 2020 00:16:17 19 Aug 2020 15:38:09 19 Aug 2020 15:37:37

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:37:37
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User closed query 'Per CDM re-query: Thank you for the update. However per previous query, please add this condition in MH else clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Dec 2020 08:02:20
User entered 'ONYCHOMYCOSIS - CREAM FOR NAIL ENAMEL TOE FUNGUS' reason for change:	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 16:27:04
Data Entry Error		
Query 'Per CDM re-query: Thank you for the update. However per previous query, please add this condition in MH else clarify. ' answered with 'UPDATED MEDICAL HISTORY WITH ONYCHOMYCOSIS (b) FEET' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 16:26:24
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	27 Nov 2020 05:56:31
User opened query 'Per CDM re-query: Thank you for the update. However per previous query, please add this condition in MH else clarify. ' (Site from DM).		27 Nov 2020 05:56:29
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'UPDATED MEDICATION TO MATCH MEDICATION RECORD SOURCE.' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 19:54:32
User entered 'CREAM FOR NAIL ENAMEL TOE FUNGUS' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 19:54:13
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:38:35

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	15 Oct 2020 04:18:28
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' answered with 'PARTICIPANT DIDNT SPECIFY AS A DIAGNOSIS' (Site from DM).	Mylene Asmar-Rios (b) (4)	02 Oct 2020 15:31:02
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)	01 Oct 2020 10:06:13
User entered 'TOE FUNGUS'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:37:37

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User closed query 'Per DM CLR: Note, 0.77% is a concentration, please update dose and dose unit with the number of applications administered (eg, Dose-1, Dose Unit-Application). Update as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	02 Mar 2021 08:37:50
Query 'Per DM CLR: Note, 0.77% is a concentration, please update dose and dose unit with the number of applications administered (eg, Dose-1, Dose Unit-Application). Update as appropriate. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	01 Mar 2021 21:09:47
User entered '1' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	01 Mar 2021 21:09:41
User opened query 'Per DM CLR: Note, 0.77% is a concentration, please update dose and dose unit with the number of applications administered (eg, Dose-1, Dose Unit-Application). Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:22:36
User entered '0.77' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	08 Dec 2020 16:23:03
User entered 'UNK'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:37:37

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 15:31:23
User entered 'Other (OTHER)' reason for change: Data Entry Error	System	02 Oct 2020 15:31:23
User opened query 'Data is required. Please complete.' (Site from System).	Mylene Asmar-Rios	02 Oct 2020 15:31:23
User entered empty.	(b) (4)	
	System	19 Aug 2020 15:37:37
	Mylene Asmar-Rios	19 Aug 2020 15:37:37
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'APPLICATION' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	17 Nov 2020 19:54:13
User entered 'UNKOWN' reason for change: Data Entry Error	(b) (4) Mylene Asmar-Rios	02 Oct 2020 15:31:23
User entered empty.	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:37:37

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:37:37
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:37:37
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Topical (TOPICAL)'	(b) (4) Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:37:37

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:37:37
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:27:43
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	19 Aug 2020 15:37:37
User entered 'UN UNK 2019'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:37:37

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	(b) (4) Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:37:37

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 16:23:00
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Aug 2020 15:37:37
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '15 Feb 2021' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 16:23:00
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 15:37:37
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:37:37
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User entered '1'	System	19 Aug 2020 15:37:37

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User entered '1'	System	19 Aug 2020 15:37:37

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:50
User entered '804 (804)'	System	19 Aug 2020 15:37:37

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: OTHER COMBINATIONS OF NUTRIENTS, PRODUCT: FISH OIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Aug 2020 15:41:28
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 Aug 2020 15:41:28
Data point term sent to Coder	System	19 Aug 2020 15:40:14
User entered 'FISH OIL'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:39:44

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Nov 2020 19:58:11
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:39:44

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'GENERAL HEALTH'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:39:44

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '900'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:39:44

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'mg (mg)'	(b) (4) Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:39:44

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:39:44
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:39:44

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:39:44
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Oral (ORAL)'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:39:44
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:39:44
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:27:43
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	19 Aug 2020 15:39:44
User entered 'UN UNK 2018'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:39:44

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:39:44

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 16:23:34
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Aug 2020 15:39:44
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'un Aug 2020' reason for change: Data Entry Error	(b) (4)	22 Feb 2021 16:23:34
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 15:39:44
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	19 Aug 2020 15:39:44
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User entered '1'	System	19 Aug 2020 15:39:44

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User entered '1'	System	19 Aug 2020 15:39:44

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:10
User entered '804 (804)'	System	19 Aug 2020 15:39:44

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: PHYTOSTEROLS NOS, PRODUCTSYNONYM: CHOLESTOFF ORIGINAL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 00:13:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 00:13:14
Data point term sent to Coder	System	19 Aug 2020 15:45:34
User entered 'cholestoff'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:44:48

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User closed query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Jan 2021 09:07:41
Query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' answered with 'UPDATED TO NO' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:12:27
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	25 Jan 2021 18:12:17
User opened query 'Per DM CLR: Prophylaxis is marked as YES. However, there is an actual condition recorded in the MH eCRF. Please review if the prophylaxis indication should be changed as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	07 Jan 2021 16:38:37
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 19:59:03
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:44:48

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'HYPERLIPIDEMIA'	(b) (4) Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:44:48

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered '900'	Mylene Asmar-Rios	19 Aug 2020 15:44:48
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	19 Aug 2020 15:44:48
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 15:44:48
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'twice daily (BID)'	Mylene Asmar-Rios	19 Aug 2020 15:44:48
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 15:44:48
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	19 Aug 2020 15:44:48
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 15:44:48
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:27:43
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	19 Aug 2020 15:44:48
User entered 'UN UNK 2020'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 15:44:48

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	19 Aug 2020 15:44:48
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	19 Aug 2020 15:44:48
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 15:44:48
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	19 Aug 2020 15:44:48
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 15:44:48

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 15:44:48

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 15:44:48

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 13:16:34
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 13:16:34
Data point term sent to Coder	System	19 Oct 2020 13:15:03
User entered 'Tylenol'	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 05:53:58
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' answered with 'ONE TIME HEADACHE WAS RESOLVED WITH ONE TYLENOLE. AS NOTED ON SAFETY CALL 4, NO NEED FOR AE. (MEF-17-NOV-2020)' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	17 Nov 2020 19:57:20

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. If the HEADACHE is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of HEADACHE did not meet the AE reporting criteria. ' (Site from DM).	(b) (4), (b) (6)	17 Nov 2020 07:40:33
User entered 'Headache Solicited AE'	Steven Anderson (b) (4) (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '500'	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'mg (mg)'	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'as needed (PRN)'	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '30 Aug 2020'	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '30 Aug 2020'	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User entered empty.	System	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User entered empty.	System	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:42
User entered empty.	System	19 Oct 2020 13:14:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: ANTIHISTAMINES FOR SYSTEMIC USE, ATC: OTHER ANTIHISTAMINES FOR SYSTEMIC USE, PRODUCT: FEXOFENADINE HYDROCHLORIDE, PRODUCTSYNONYM: ALLEGRA - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 13:16:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Oct 2020 13:16:35
Data point term sent to Coder	System	19 Oct 2020 13:16:04
User entered 'Allegra'	Steven Anderson (b) (4)	19 Oct 2020 13:15:31

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Seasonal Allergies'	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered '180'	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'mg (mg)'	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'as needed (PRN)'	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'un UNK 2020'	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered '0'	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	19 Oct 2020 13:15:31
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 13:15:31

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 13:15:31

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 13:15:31

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: DIURETICS, ATC: POTASSIUM-SPARING AGENTS, ATC: ALDOSTERONE ANTAGONISTS, PRODUCT: SPIRONOLACTONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Dec 2020 13:55:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Dec 2020 13:55:01
Data point term sent to Coder	System	06 Dec 2020 13:54:12
User entered 'SPIRONOLACTONE'	Melissa Fuson (b) (4) (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'HYPERTENSION'	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '25'	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'mg (mg)'	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'UN UNK 2018'	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'UN Nov 2020'	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	Melissa Fuson (b) (4)	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User entered '1'	System	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User entered '1'	System	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:24:29
User entered '804 (804)'	System	06 Dec 2020 13:53:38

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User closed query 'Per DM CLR: Con Med LOSARTAN was added/changed on UN SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:03:59
Query 'Per DM CLR: Con Med LOSARTAN was added/changed on UN SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'this was not deemed as a worsening event and PI elected to not write it up as an ae due to PI discretion after reviewing information with subject' (Site from DM).	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 17:48:21
User opened query 'Per DM CLR: Con Med LOSARTAN was added/changed on UN SEP 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:56:01
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 14:21:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 14:21:56
Data point term sent to Coder	System	09 Mar 2021 14:20:51
User entered 'losartan'	Andrea Newlands (b) (4) (b) (4)	09 Mar 2021 14:20:02

PRODUCTION RELEASE (v12.003
EAB) (1725)

2005 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'hypertension'	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered '50'	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'un Sep 2020'	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Mar 2021 14:20:02
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 14:20:02

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Mar 2021 14:20:02

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Mar 2021 14:20:02

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	02 Mar 2021 17:28:44
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Mar 2021 17:28:44
Data point term sent to Coder Coding entries removed.	System Andrea Newlands (b) (4)	02 Mar 2021 17:27:39 02 Mar 2021 17:27:05
User entered 'ATEnOLOL' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	02 Mar 2021 17:27:05
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Dec 2020 13:55:53
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Dec 2020 13:55:53
Data point term sent to Coder User entered 'ATEROLOL'	System Melissa Fuson (b) (4) (b) (4)	06 Dec 2020 13:55:12 06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'HYPERTENSION'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '25'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	06 Dec 2020 13:54:39
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	06 Dec 2020 13:54:39
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	06 Dec 2020 13:54:39
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Oral (ORAL)'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	06 Dec 2020 13:54:39
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'UN Nov 2020'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	06 Dec 2020 13:54:39
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Dec 2020 13:54:39

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	11 Dec 2020 09:26:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	11 Dec 2020 09:26:50
Data point term sent to Coder	System	06 Dec 2020 13:58:13
User entered 'EZETIMIB E'	Melissa Fuson (b) (4) (b) (4)	06 Dec 2020 13:57:36

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	06 Dec 2020 13:57:36
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'HYPERLIPIDEMIA'	Melissa Fuson (b) (4)	06 Dec 2020 13:57:36

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered '10'	Melissa Fuson (b) (4)	06 Dec 2020 13:57:36
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'mg (mg)'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:57:36

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:57:36

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	06 Dec 2020 13:57:36
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	06 Dec 2020 13:57:36
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	06 Dec 2020 13:57:36
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	06 Dec 2020 13:57:36
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'UN Nov 2020'	Melissa Fuson (b) (4)	06 Dec 2020 13:57:36

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	(b) (4) Melissa Fuson (b) (4)	06 Dec 2020 13:57:36

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	06 Dec 2020 13:57:36
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	06 Dec 2020 13:57:36
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	06 Dec 2020 13:57:36
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Dec 2020 13:57:36

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	06 Dec 2020 13:57:36

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	06 Dec 2020 13:57:36

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
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.	(b) (4) Coder Import (b) (4)	12 Apr 2021 18:22:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 18:22:28
Data point term sent to Coder Coding entries removed.	System Steven Anderson (b) (4)	12 Apr 2021 17:34:58 12 Apr 2021 17:34:50
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)	09 Mar 2021 14:39:56
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Mar 2021 14:39:56
Data point term sent to Coder User entered 'mucinex'	System Andrea Newlands (b) (4)	09 Mar 2021 14:23:58 09 Mar 2021 14:23:11

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User closed query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	13 Apr 2021 12:04:20
Query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' answered with 'this has been updated to SAR due to this being the reason the subject would take this medication. ' (Site from DM).	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 17:35:35
User entered 'Seasonal Allergic Rhinitis.' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	12 Apr 2021 17:34:50
User opened query 'Per DM CLR: Please note there is no Med History condition or AE that matches this Con Med indication. Please review the Con Med use and add a medical condition and all applicable details to the appropriate Med History or AE eCRF.Per DM CLR: Please provide the actual dose for this medication instead of number of tablets as there are other dosage options for this drug. Update Con Med eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	29 Mar 2021 10:57:01
User entered 'post-nasal drainage'	Andrea Newlands (b) (4) (b) (4)	09 Mar 2021 14:23:11

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered '1'	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'tablet (TABLET)'	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'un UNK 2018'	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Mar 2021 14:23:11
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 14:23:11

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 14:23:11

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Mar 2021 14:23:11

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	15 Apr 2021 16:10:07
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Apr 2021 16:10:07
Data point term sent to Coder	System	15 Apr 2021 16:09:01
User entered 'Aspirin'	(b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Heart health'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '81'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 16:08:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 01:22:05
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 Apr 2021 01:22:05
Data point term sent to Coder	System	15 Apr 2021 16:10:01
User entered 'carvedilol'	(b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Hypertension and heart health'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '6.25'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 16:09:54

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	16 Apr 2021 01:32:10
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 Apr 2021 01:32:10
Data point term sent to Coder	System	15 Apr 2021 16:12:03
User entered 'clopidogrel'	(b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Heart health'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '75'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 16:11:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE MONONITRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 02:01:14
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 Apr 2021 02:01:14
Data point term sent to Coder	System	15 Apr 2021 16:14:05
User entered 'isosorbide mononitrate'	(b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'heart health'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '30'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	15 Apr 2021 16:13:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	16 Apr 2021 09:10:22
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 Apr 2021 09:10:22
Data point term sent to Coder	System	15 Apr 2021 16:15:06
User entered 'nitroglycerin'	(b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'heart health/chest pain'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0.4'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '09 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '0'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	15 Apr 2021 16:14:30

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:28:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:28:19
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:43
Data point term sent to Coder	System	21 Apr 2021 19:12:29
User entered 'Fentanyl'	Steven Anderson (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered 'AMI'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered '50'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered 'ug (ug)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered 'once (ONCE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered '6 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered '6 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:43
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User entered empty.	System	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User entered empty.	System	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:41
User entered empty.	System	21 Apr 2021 19:12:12

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 07:20:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 07:20:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:47
Data point term sent to Coder	System	21 Apr 2021 19:13:30
User entered 'versed'	Steven Anderson (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered 'AMi'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered 'l'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered 'mg (mg)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered 'once (ONCE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered '6 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered '6 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:47
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User entered empty.	System	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User entered empty.	System	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:17
User entered empty.	System	21 Apr 2021 19:12:57

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON, PRODUCTSYNONYM: ZOFRAN [ONDANSETRON] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Apr 2021 20:02:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Apr 2021 20:02:21
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:52
Data point term sent to Coder	System	21 Apr 2021 19:14:31
User entered 'zofran'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered 'nausea prophylaxis'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered '4'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered 'mg (mg)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered 'once (ONCE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered '6 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:52
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User entered empty.	System	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User entered empty.	System	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:36
User entered empty.	System	21 Apr 2021 19:13:42

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:47:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:47:44
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:23:56
Data point term sent to Coder	System	21 Apr 2021 19:15:31
User entered 'lidocaine 1%'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered 'PCI procedure'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered '10/1' reason for change: Data Entry Error	Steven Anderson (b) (4)	21 Apr 2021 19:16:36
User entered '5/10'	(b) (4) Steven Anderson (b) (4)	21 Apr 2021 19:15:06
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered 'Other (OTHER)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered 'mg/mL'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered 'once (ONCE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered 'Subcutaneous (SUBCUTANEOUS)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered '6 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered '6 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:23:56
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User entered empty.	System	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User entered empty.	System	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:40
User entered empty.	System	21 Apr 2021 19:15:06

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: PHENYLALKYLAMINE DERIVATIVES, PRODUCT: VERAPAMIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 06:14:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 06:14:53
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:24:01
Data point term sent to Coder	System	21 Apr 2021 19:16:33
User entered 'verapamil'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered 'PCI procedure'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered '5/10'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered 'Other (OTHER)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered 'mg/ml'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered 'once (ONCE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered '6 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered '6 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:01
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User entered empty.	System	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User entered empty.	System	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:09:48
User entered empty.	System	21 Apr 2021 19:16:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 06:00:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 06:00:46
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:24:31
Data point term sent to Coder	System	21 Apr 2021 19:18:36
User entered 'Nitroglycerin'	Steven Anderson (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered 'PCI procedure'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered '150'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User closed query 'should unit be mcg? Please confirm and update accordingly' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:42:28
DataPoint Verified.		21 Apr 2021 19:42:17
Query 'should unit be mcg? Please confirm and update accordingly' answered with 'this has been updated accordingly' (Site from CRA).	Steven Anderson (b) (4)	21 Apr 2021 19:29:41
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	21 Apr 2021 19:29:31
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:24:36
DataPoint Verified.		21 Apr 2021 19:24:31
User opened query 'should unit be mcg? Please confirm and update accordingly' (Site from CRA).		21 Apr 2021 19:22:31
User entered 'mg (mg)'	Steven Anderson (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered 'once (ONCE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:31
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User entered empty.	System	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User entered empty.	System	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:10:10
User entered empty.	System	21 Apr 2021 19:18:33

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:31:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:31:42
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:24:04
Data point term sent to Coder	System	21 Apr 2021 19:19:38
User entered 'heparin'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered 'thrombus prophylaxis'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered '10,000'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered 'IU (IU)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered 'once (ONCE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:04
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User entered empty.	System	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User entered empty.	System	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:23
User entered empty.	System	21 Apr 2021 19:19:32

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:33:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:33:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:24:09
Data point term sent to Coder	System	21 Apr 2021 19:20:39
User entered 'Heparin'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered 'thrombus prophylaxes'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered '2500'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered 'IU (IU)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered 'once (ONCE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:09
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User entered empty.	System	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User entered empty.	System	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:28
User entered empty.	System	21 Apr 2021 19:20:34

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:33:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:33:48
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:24:12
Data point term sent to Coder	System	21 Apr 2021 19:21:40
User entered 'Heparin'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered 'thrombus prophylaxes'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered '1000'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered 'IU (IU)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered 'once (ONCE)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:24:12
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User entered empty.	System	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User entered empty.	System	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:58
User entered empty.	System	21 Apr 2021 19:21:18

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4), (b) (6)	22 Apr 2021 14:07:13
User closed query 'Please confirm spelling and update as appropriate. EPTIFIBATIDE per source' (Site from CRA).		22 Apr 2021 14:06:56
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: EPTIFIBATIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Apr 2021 13:04:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	22 Apr 2021 13:04:58
Query 'Please confirm spelling and update as appropriate. EPTIFIBATIDE per source' answered with 'this has been corrected' (Site from CRA).	Steven Anderson (b) (4)	22 Apr 2021 12:51:13
Data point term sent to Coder	System	22 Apr 2021 12:50:45
Coding entries removed.	Steven Anderson (b) (4)	22 Apr 2021 12:50:20
User entered 'EPTIFIBATIDE' reason for change: Data Entry Error	(b) (4)	22 Apr 2021 12:50:20
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: EPTIFIBATIDE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	22 Apr 2021 05:25:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	(b) (4)	22 Apr 2021 05:25:49
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:50:41
DataPoint Verified.		21 Apr 2021 19:50:36

PRODUCTION RELEASE (v12.003
EAB) (1725)

2329 of 2537

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'Please confirm spelling and update as appropriate. EPTIFIBATIDE per source' (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 19:47:07
Data point term sent to Coder	System	21 Apr 2021 19:27:50
User entered 'eptifibalide'	Steven Anderson (b) (4)	21 Apr 2021 19:27:16
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered 'AMI'	Steven Anderson (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered '14,292'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered 'ug (ug)'	Steven Anderson (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered 'once (ONCE)'	Steven Anderson (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:36
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User entered empty.	System	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User entered empty.	System	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:11:17
User entered empty.	System	21 Apr 2021 19:27:16

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: HEPARIN GROUP, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	22 Apr 2021 05:33:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Apr 2021 05:33:02
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:50:23
Data point term sent to Coder	System	21 Apr 2021 19:28:53
User entered 'heparin'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered 'Yes (Y)'	Steven Anderson (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered 'thrombus prophylactic'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered '1000'	Steven Anderson (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered 'IU (IU)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered 'once (ONCE)'	Steven Anderson (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered 'Intravenous (INTRAVENOUS)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered '0'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered '06 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:50:23
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User entered empty.	System	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User entered empty.	System	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:12:03
User entered empty.	System	21 Apr 2021 19:28:08

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 14:09:22
User closed query 'Please confirm spelling and update as appropriate. ISOSORBIDE MONONITRATE per source' (Site from CRA).		22 Apr 2021 14:09:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE MONONITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 13:13:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
Query 'Please confirm spelling and update as appropriate. ISOSORBIDE MONONITRATE per source' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	22 Apr 2021 12:53:34
Data point term sent to Coder	System	22 Apr 2021 12:52:55
Coding entries removed.	Steven Anderson (b) (4)	22 Apr 2021 12:52:40
	(b) (4)	
Coding entries removed.	Steven Anderson (b) (4)	22 Apr 2021 12:52:40
	(b) (4)	
User entered 'ISOSORBIDE MONONITRATE' reason for change: Data Entry Error	Steven Anderson (b) (4)	22 Apr 2021 12:52:40
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE MONONITRATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Apr 2021 05:45:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	21 Apr 2021 19:55:21

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:24
User opened query 'Please confirm spelling and update as appropriate. ISOSORBIDE MONONITRATE per source' (Site from CRA).		21 Apr 2021 19:51:31
Data point term sent to Coder	System	21 Apr 2021 19:29:53
User entered 'isosorbide monoitrate'	Steven Anderson (b) (4)	21 Apr 2021 19:28:59
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:59

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Apr 2021 14:09:54
User closed query 'Please correct spelling of PROPHYLAXIS' (Site from CRA).		22 Apr 2021 14:09:42
Query 'Please correct spelling of PROPHYLAXIS' answered with 'this has been updated' (Site from CRA).	Steven Anderson (b) (4)	22 Apr 2021 12:53:56
	(b) (4)	
DataPoint Un-verified.	Steven Anderson (b) (4)	22 Apr 2021 12:52:40
	(b) (4)	
User entered 'CHEST PAIN PROPHYLAXIS' reason for change: Data Entry Error	Steven Anderson (b) (4)	22 Apr 2021 12:52:40
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 19:53:24
User opened query 'Please correct spelling of PROPHYLAXIS' (Site from CRA).		21 Apr 2021 19:51:55
User entered 'Chest pain prophylaxes'	Steven Anderson (b) (4)	21 Apr 2021 19:28:59
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered '30'	Steven Anderson (b) (4)	21 Apr 2021 19:28:59
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered 'mg (mg)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:59

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:59

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered 'once daily (QD)'	Steven Anderson (b) (4)	21 Apr 2021 19:28:59
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:59

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	21 Apr 2021 19:28:59
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:59

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered '09 Mar 2021'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:59

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered '0'	Steven Anderson (b) (4)	21 Apr 2021 19:28:59
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:59

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered empty.	Steven Anderson (b) (4)	21 Apr 2021 19:28:59
	(b) (4)	

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 19:53:24
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	21 Apr 2021 19:28:59

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:28:59

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Apr 2021 19:28:59

US3412059

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:29:39

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Apr 2021 19:28:59

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:29:39

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:25
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:22
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	08 Mar 2021 19:28:10
User entered 'No (N)'	(b) (4), (b) (6)	10 Aug 2020 20:27:54

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:29:39

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:22
	(b) (4)	
User entered '11 Feb 2021'	Steven Anderson (b) (4)	08 Mar 2021 19:28:28
	(b) (4)	

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:29:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:22
	(b) (4)	
User entered 'DUPLEX SCAN VENOUS STUDY'	Steven Anderson (b) (4)	08 Mar 2021 19:28:28
	(b) (4)	

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:22
	(b) (4)	
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	08 Mar 2021 19:28:28
	(b) (4)	

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:29:39

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:22
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	08 Mar 2021 19:28:28
	(b) (4)	

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:29:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:16
DataPoint Verified.		21 Apr 2021 20:04:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:53:48

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:29:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:16
DataPoint Verified.		21 Apr 2021 20:04:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'ECG'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:53:48

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:16
DataPoint Verified.		21 Apr 2021 20:04:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:53:48

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:29:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:16
DataPoint Verified.		21 Apr 2021 20:04:37
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:53:48

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:29:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:17
DataPoint Verified.		21 Apr 2021 20:06:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:57:37

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:29:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:17
DataPoint Verified.		21 Apr 2021 20:06:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'transthoracic echo (TTE)' reason for change: Data Entry Error	(b) (4)	(b) (4)
User entered 'TTE'	(b) (4), (b) (6)	15 Apr 2021 16:04:36
		15 Apr 2021 15:57:37

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:17
DataPoint Verified.		21 Apr 2021 20:06:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:57:37

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:29:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:17
DataPoint Verified.		21 Apr 2021 20:06:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:57:37

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:29:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:20
DataPoint Verified.		21 Apr 2021 20:05:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:04

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:29:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:20
DataPoint Verified.		21 Apr 2021 20:05:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Chest xray'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:04

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:20
DataPoint Verified.		21 Apr 2021 20:05:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:04

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:29:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:20
DataPoint Verified.		21 Apr 2021 20:05:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 15:58:04

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:29:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:22
DataPoint Verified.		21 Apr 2021 20:04:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:03:49

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:29:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:22
DataPoint Verified.		21 Apr 2021 20:07:05
Query 'Please clarify procedure. Coronary angiography and L heart cath performed per source' canceled (Site from CRA).		21 Apr 2021 20:07:04
User opened query 'Please clarify procedure. Coronary angiography and L heart cath performed per source' (Site from CRA).		21 Apr 2021 20:04:23
Query 'Please clarify procedure' canceled (Site from CRA).		21 Apr 2021 20:04:01
User opened query 'Please clarify procedure' (Site from CRA).		21 Apr 2021 20:03:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Coronary angiography with LV'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:03:49

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:22
DataPoint Verified.		21 Apr 2021 20:04:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:03:49

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:29:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:22
DataPoint Verified.		21 Apr 2021 20:04:29
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:03:49

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:29:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:23
DataPoint Verified.		21 Apr 2021 19:59:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:05:58

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:29:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:23
DataPoint Verified.		21 Apr 2021 19:59:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'cardiac catheterization'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:05:58

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:23
DataPoint Verified.		21 Apr 2021 19:59:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:05:58

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:29:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:23
DataPoint Verified.		21 Apr 2021 19:59:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:05:58

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:29:39

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:26
DataPoint Verified.		21 Apr 2021 20:08:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered '06 Mar 2021'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:16:20

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:29:39

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:26
DataPoint Verified.		21 Apr 2021 20:08:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered 'COvid-19 swab'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 16:16:20

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:29:39

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:26
DataPoint Verified.		21 Apr 2021 20:08:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
	(b) (4)	
User closed query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	15 Apr 2021 16:16:32
User opened query 'Indication is not Other, however specify has been provided. Please correct.' (Site from System).	System	15 Apr 2021 16:16:20
User entered 'Adverse Event (AE)'	(b) (4), (b) (6)	15 Apr 2021 16:16:20

US3412059

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:29:39

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:26
DataPoint Verified.		21 Apr 2021 20:08:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:25
User entered empty; reason for change Data Entry Error	(b) (4)	(b) (4), (b) (6)
User entered 'results were negative'		15 Apr 2021 16:16:20

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:14
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:54
Un-reviewed for Safety.		15 Apr 2021 19:18:51
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'USA-US061-2021-MRNA-1273-P301000014'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:58
User entered 'Yes (Y)'	System	22 Mar 2021 12:32:17
Un-reviewed for Safety.	System	22 Mar 2021 12:31:58
User entered 'No (N)'	System	22 Mar 2021 12:31:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered 'Richard'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gregory'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered 'Powell'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gottschlich'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '4260 Glendale Milford Road'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Cincinnati'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'OH'	(b) (4) System	15 Apr 2021 19:19:42

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '45242'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User entered 'US'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:15:43
User entered '5'	System	29 Apr 2021 21:09:59
User entered '4'	System	21 Apr 2021 20:37:34
User entered '3'	System	15 Apr 2021 19:19:42
User entered '2'	System	23 Mar 2021 15:10:19
User entered '1'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:14
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:54
Un-reviewed for Safety.		15 Apr 2021 19:18:51
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'USA-US061-2021-MRNA-1273-P301000014'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:58
User entered 'Yes (Y)'	System	22 Mar 2021 12:32:17
Un-reviewed for Safety.	System	22 Mar 2021 12:31:58
User entered 'No (N)'	System	22 Mar 2021 12:31:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	
User entered 'Richard'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:42
	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gregory'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered 'Powell'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gottschlich'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '4260 Glendale Milford Road'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Cincinnati'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'OH'	(b) (4) System	15 Apr 2021 19:19:42

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '45242'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:58
User entered 'US'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:15:43
User entered '5'	System	29 Apr 2021 21:09:59
User entered '4'	System	21 Apr 2021 20:37:34
User entered '3'	System	15 Apr 2021 19:19:42
User entered '2'	System	23 Mar 2021 15:10:19
User entered '1'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:29:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '09/Mar/2021 11:18'	(b) (4) System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:29:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User entered 'I'	(b) (4), (b) (6)	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:14
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:54
Un-reviewed for Safety.		15 Apr 2021 19:18:51
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'USA-US061-2021-MRNA-1273-P301000014'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:58
User entered 'Yes (Y)'	System	22 Mar 2021 12:32:17
Un-reviewed for Safety.	System	22 Mar 2021 12:31:58
User entered 'No (N)'	System	22 Mar 2021 12:31:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered 'Richard'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gregory'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	
User entered 'Powell'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:42
	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gottschlich'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '4260 Glendale Milford Road'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Cincinnati'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'OH'	(b) (4) System	15 Apr 2021 19:19:42

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '45242'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:58
User entered 'US'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:15:43
User entered '5'	System	29 Apr 2021 21:09:59
User entered '4'	System	21 Apr 2021 20:37:34
User entered '3'	System	15 Apr 2021 19:19:42
User entered '2'	System	23 Mar 2021 15:10:19
User entered '1'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:29:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '23/Mar/2021 11:10'	(b) (4) System	23 Mar 2021 15:10:19

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:29:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:58
User entered 'I'		23 Mar 2021 15:10:19

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:14
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:54
Un-reviewed for Safety.		15 Apr 2021 19:18:51
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'USA-US061-2021-MRNA-1273-P301000014'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:58
User entered 'Yes (Y)'	System	22 Mar 2021 12:32:17
Un-reviewed for Safety.	System	22 Mar 2021 12:31:58
User entered 'No (N)'	System	22 Mar 2021 12:31:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	
User entered 'Richard'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:42
	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gregory'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	
User entered 'Powell'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:42
	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gottschlich'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:42
	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '4260 Glendale Milford Road'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Cincinnati'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'OH'	(b) (4) System	15 Apr 2021 19:19:42

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Site Address: [Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '45242'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User entered 'US'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:15:43
User entered '5'	System	29 Apr 2021 21:09:59
User entered '4'	System	21 Apr 2021 20:37:34
User entered '3'	System	15 Apr 2021 19:19:42
User entered '2'	System	23 Mar 2021 15:10:19
User entered '1'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:29:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered '15/Apr/2021 15:19'	(b) (4) System	15 Apr 2021 19:19:42

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:29:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'I'	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:19:42

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:14
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:54
Un-reviewed for Safety.		15 Apr 2021 19:18:51
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'USA-US061-2021-MRNA-1273-P301000014'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User entered 'Yes (Y)'	System	22 Mar 2021 12:32:17
Un-reviewed for Safety.	System	22 Mar 2021 12:31:58
User entered 'No (N)'	System	22 Mar 2021 12:31:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	
User entered 'Richard'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:42
	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gregory'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered 'Powell'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gottschlich'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '4260 Glendale Milford Road'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Site Address: City

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Cincinnati'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'OH'	(b) (4) System	15 Apr 2021 19:19:42

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Site Address: Postal Code

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:42
	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '45242'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:58
User entered 'US'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:15:43
User entered '5'	System	29 Apr 2021 21:09:59
User entered '4'	System	21 Apr 2021 20:37:34
User entered '3'	System	15 Apr 2021 19:19:42
User entered '2'	System	23 Mar 2021 15:10:19
User entered '1'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:29:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:16
User entered '21/Apr/2021 16:37'	(b) (4) System	21 Apr 2021 20:37:34

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:29:39

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)	26 Apr 2021 14:39:16
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
User entered 'I'		21 Apr 2021 20:37:34

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:14
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:54
Un-reviewed for Safety.		15 Apr 2021 19:18:51
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'USA-US061-2021-MRNA-1273-P301000014'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:58
User entered 'Yes (Y)'	System	22 Mar 2021 12:32:17
Un-reviewed for Safety.	System	22 Mar 2021 12:31:58
User entered 'No (N)'	System	22 Mar 2021 12:31:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered 'Richard'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gregory'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered 'Powell'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gottschlich'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Site Address: [Street](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '4260 Glendale Milford Road'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Cincinnati'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'OH'	(b) (4) System	15 Apr 2021 19:19:42

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '45242'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:58
User entered 'US'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:15:43
User entered '5'	System	29 Apr 2021 21:09:59
User entered '4'	System	21 Apr 2021 20:37:34
User entered '3'	System	15 Apr 2021 19:19:42
User entered '2'	System	23 Mar 2021 15:10:19
User entered '1'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:29:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	29 Apr 2021 23:55:50
User entered '29/Apr/2021 17:09'	(b) (4) System	29 Apr 2021 21:09:59

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:29:39

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:17:23
User signature succeeded.	Richard Powell (b) (4)	29 Apr 2021 23:55:50
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Apr 2021 21:09:59

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[SAEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:14
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:54
Un-reviewed for Safety.		15 Apr 2021 19:18:51
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'USA-US061-2021-MRNA-1273-P301000014'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Serious

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Death

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:18:58
User entered 'Yes (Y)'	System	22 Mar 2021 12:32:17
Un-reviewed for Safety.	System	22 Mar 2021 12:31:58
User entered 'No (N)'	System	22 Mar 2021 12:31:58
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'Yes (Y)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:18
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:10
Reviewed for Safety.	(b) (4), (b) (6)	09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'No (N)'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's First Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered 'Richard'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gregory'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator's Last Name](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered 'Powell'	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Gottschlich'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

Site Address: Street

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:42
	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '4260 Glendale Milford Road'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: City](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:42
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered 'Cincinnati'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: State](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
User entered 'OH'	(b) (4) System	15 Apr 2021 19:19:42

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	21 Apr 2021 20:37:56
DataPoint Verified.		21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Un-reviewed for Safety.	(b) (4)	
User entered empty.	System	15 Apr 2021 19:19:42
Reviewed for Safety.	System	15 Apr 2021 19:19:42
	(b) (4), (b) (6)	15 Apr 2021 19:19:28
Un-reviewed for Safety.		15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		09 Mar 2021 16:18:12
User entered '45242'	System	09 Mar 2021 16:17:55

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[Investigator Country](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 13:35:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:54:53
Reviewed for Safety.	(b) (4)	15 Apr 2021 19:19:28
Un-reviewed for Safety.	(b) (4), (b) (6)	15 Apr 2021 19:19:25
Reviewed for Safety.		15 Apr 2021 19:19:18
Un-reviewed for Safety.		15 Apr 2021 19:19:10
Reviewed for Safety.		15 Apr 2021 19:18:58
User entered 'US'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:39

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '6'	System	30 Apr 2021 17:15:43
User entered '5'	System	29 Apr 2021 21:09:59
User entered '4'	System	21 Apr 2021 20:37:34
User entered '3'	System	15 Apr 2021 19:19:42
User entered '2'	System	23 Mar 2021 15:10:19
User entered '1'	System	09 Mar 2021 16:18:21

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:29:39

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	30 Apr 2021 17:22:02
User entered '30/Apr/2021 13:15'	(b) (4) System	30 Apr 2021 17:15:43

US3412059

Folder: SAE USA-US061-2021-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:29:39

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)	30 Apr 2021 17:22:02
Reviewed for Safety.	(b) (4), (b) (6)	30 Apr 2021 17:17:23
User entered 'I'		30 Apr 2021 17:15:43