

US3412067 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:29:16

All time stamps listed in this document are displayed in GMT

US3412067

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:09:25

Generated On: 09 Jun 2021 17:29:16

Participant ID

US3412067

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

US3412067

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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

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Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Date of Birth (MMM yyyy)	(b) (6) 1959
Age	60
Age Units	YEARS
Age (Derived)	60
Sex	Female <input type="radio"/> Male <input checked="" type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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 ☒
Amendment 2 ☐
Amendment 3 ☐
Amendment 4 ☐
Amendment 5 ☐

Was participant enrolled in the study? Yes ☒
No ☐

If No, indicate reason for screen fail Withdrew Consent ☐
Inclusion/Exclusion ☐
Cohort Full ☐
Other ☐

If reason for screen fail is Other, specify _____
Was this participant screened previously? Yes ☐
No ☒

If Yes, previous participant number _____
Enrollment Trigger 1

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Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:25:17

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Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Condition	SLEEP APNEA
Start date (dd MMM yyyy)	31 JUL 2020
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)	JUL 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Condition	HYPERLIPIDEMIA
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Condition	HYPERTENSION
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Condition	BPH
Start date (dd MMM yyyy)	UN MAR 2020
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)	MAR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Condition	OSTEOARTHRITIS - BILATERAL KNEES, LOWER BACK, NECK, HANDS, FEET.
Start date (dd MMM yyyy)	UN UNK 2005
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 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Condition	TYPE 2 DIABETES
Start date (dd MMM yyyy)	UN UNK 2010
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy) _____	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2010
Start Year (derived)	2010
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Condition	NECK SURGERY - CERVICAL FUSION
Start date (dd MMM yyyy)	15 APR 2020
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	15 APR 2020
Stop date completely unknown	False
Start Month and Year (derived)	APR 2020
Start Year (derived)	2020
Stop Month and Year (derived)	APR 2020
Stop Year (derived)	2020

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Condition	RIGHT KNEE SEPTIC JOINT SURGERY
Start date (dd MMM yyyy)	UN UNK 2015
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2015
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2015
Start Year (derived)	2015
Stop Month and Year (derived)	JAN 2015
Stop Year (derived)	2015

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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>)	10:33 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 10:33
Height (<i>xxx.x</i>)	174.0 cm
Weight (<i>xxx.x</i>)	92.9 kg
BMI (<i>xxx.x</i>)	30.68437 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)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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.

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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

LIVES WITH A ESSENTIAL
WORKER

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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

What was the participant's randomization number? 142425

In what Cohort was the participant enrolled?
 >=18 and <65 years and not at risk ☐
 >=18 and <65 years and at risk ☒
 >=65 years ☐

If participant is considered at risk, please check all that apply (If any are checked as Yes, please ensure the actual condition is recorded on the Medical History form)

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma) Yes ☐ No ☒

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension) Yes ☐ No ☒

Severe obesity (body mass index > or = 40kg/m2) Yes ☐ No ☒

Diabetes (Type I, Type 2, or gestational) Yes ☒ No ☐

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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)	10:33 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 10:33
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)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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)	12:58 (24 HR)
Vital Signs Date and Time (derived)	31 JUL 2020 12:58
Temperature (xxx.x)	97.0 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	62 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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) 12:10 (24 HR)

Treatment Date and Time (derived) 31 JUL 2020 12:10

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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)	11:12 (24 HR)
Collection date and time (derived)	31 JUL 2020 11:12

US3412067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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	11:00	31 JUL 2020 11:00
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 JUL 2020 13:07

PC Open Date & Time

31 JUL 2020 12:30

PC Close Date & Time

31 JUL 2020 15:00

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 97.4 °F

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

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

PC Time Stamp	31 JUL 2020 18:15
PC Open Date & Time	31 JUL 2020 15:55
PC Close Date & Time	01 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

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

01 AUG 2020 17:34

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

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

97.2 °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 AUG 2020 17:47

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 05:43

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

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

97.2 °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

04 AUG 2020 17:43

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

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

97.3 °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 19:26

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 18:08

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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 13:08

PC Open Date & Time

31 JUL 2020 12:30

PC Close Date & Time

31 JUL 2020 15:00

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 18:16

PC Open Date & Time

31 JUL 2020 15:55

PC Close Date & Time

01 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

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

01 AUG 2020 17:34

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

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

02 AUG 2020 17:48

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

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

04 AUG 2020 05:43

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

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 17:44

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

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 19:27

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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 18:09

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 13:09
PC Open Date & Time	31 JUL 2020 12:30
PC Close Date & Time	31 JUL 2020 15:00

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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

No ☒

Yes ☐

PC Time stamp	31 JUL 2020 18:18
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PC Open Date & Time	31 JUL 2020 15:55
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PC Close Date & Time	01 AUG 2020 11:59
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US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

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 ☒

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 17:35
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

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 ☒

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 17:49
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

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
EAB) (1725)

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US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 05:44
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

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
EAB) (1725)

57 of 2488

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 17:45
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 19:27
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

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 ☒

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 18:09
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3412067

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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)	09:03 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 09:03
Temperature (xxx.x)	36.6 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	126 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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)	10:17 (24 HR)
Vital Signs Date and Time (derived)	28 AUG 2020 10:17
Temperature (xxx.x)	96.5 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3412067

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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.

US3412067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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) 09:45 (24 HR)

Treatment Date and Time (derived) 28 AUG 2020 09:45

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

US3412067

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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)	09:28 (24 HR)
Collection date and time (derived)	28 AUG 2020 09:28

US3412067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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	09:34	28 AUG 2020 09:34
Nasopharyngeal Swab 2	No		

US3412067

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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

96.5 °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

28 AUG 2020 10:23

PC Open Date & Time

28 AUG 2020 10:05

PC Close Date & Time

28 AUG 2020 12:35

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 97.7 °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	28 AUG 2020 18:05
PC Open Date & Time	28 AUG 2020 13:30
PC Close Date & Time	29 AUG 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

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

97.2 °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 18:44

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

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

97.8 °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

30 AUG 2020 20:34

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

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

31 AUG 2020 17:38

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

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

97.9 °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

01 SEP 2020 20:47

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 SEP 2020 20:54

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

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

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

Yes ☐

No ☐

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

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

To **PREVENT** pain or fever from occurring

PC Time Stamp

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

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

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

28 AUG 2020 10:25

PC Open Date & Time

28 AUG 2020 10:05

PC Close Date & Time

28 AUG 2020 12:35

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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

28 AUG 2020 18:07

PC Open Date & Time

28 AUG 2020 13:30

PC Close Date & Time

29 AUG 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

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 18:44

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

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 20:34

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

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 17:39

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

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 20:48

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

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 20:55

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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 ☐

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

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

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

Yes ☐

No ☐

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

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

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

None ☐

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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

No ☒

Yes ☐

PC Time stamp	28 AUG 2020 10:26
PC Open Date & Time	28 AUG 2020 10:05
PC Close Date & Time	28 AUG 2020 12:35

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 13:30
PC Close Date & Time	29 AUG 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

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 ☒

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 18:45
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 20:36
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

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 ☒

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 17:40
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 5

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 20:49
PC Open Date & Time	01 SEP 2020 12:00
PC Close Date & Time	02 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

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 ☒

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 20:57
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

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EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

Yes ☐

PC Time stamp

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 15:57

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412067

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	04 SEP 2020 15:57
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412067

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:25:17

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	25 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

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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) _____

US3412067

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

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.

US3412067

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	25 SEP 2020
Collection time (00:00-23:59)	08:28 (24 HR)
Collection date and time (derived)	25 SEP 2020 08:28

US3412067

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:48:44

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 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°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="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"/>

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

30 SEP 2020 00:01

Patient Cloud Close Date & Time

04 OCT 2020 23:59

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 08:03:22

Patient Cloud Open Date & Time

07 OCT 2020 00:01

Patient Cloud Close Date & Time

11 OCT 2020 23:59

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 <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	18 OCT 2020 09:15:28
Patient Cloud Open Date & Time	14 OCT 2020 00:01
Patient Cloud Close Date & Time	18 OCT 2020 23:59

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 92

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

31 OCT 2020 05:18:15

Patient Cloud Open Date & Time

28 OCT 2020 00:01

Patient Cloud Close Date & Time

01 NOV 2020 23:59

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 99

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

04 NOV 2020 05:23:59

Patient Cloud Open Date & Time

04 NOV 2020 00:01

Patient Cloud Close Date & Time

08 NOV 2020 23:59

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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°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="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"/>

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Patient Cloud Close Date & Time

15 NOV 2020 23:59

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 <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°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="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"/>

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

Patient Cloud Open Date & Time

18 NOV 2020 00:01

Patient Cloud Close Date & Time

22 NOV 2020 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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 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"/>
Have 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	25 NOV 2020 12:59:40
Patient Cloud Open Date & Time	22 NOV 2020 00:01
Patient Cloud Close Date & Time	26 NOV 2020 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

29 NOV 2020 07:29:19

Patient Cloud Open Date & Time

29 NOV 2020 00:01

Patient Cloud Close Date & Time

03 DEC 2020 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 131

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

06 DEC 2020 07:45:08

Patient Cloud Open Date & Time

06 DEC 2020 00:01

Patient Cloud Close Date & Time

10 DEC 2020 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 05:41:37

Patient Cloud Open Date & Time

13 DEC 2020 00:01

Patient Cloud Close Date & Time

17 DEC 2020 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 16:11:24

Patient Cloud Open Date & Time

20 DEC 2020 00:01

Patient Cloud Close Date & Time

24 DEC 2020 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 06:51:40

Patient Cloud Open Date & Time

27 DEC 2020 00:01

Patient Cloud Close Date & Time

31 DEC 2020 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

06 JAN 2021 09:17:37

Patient Cloud Open Date & Time

03 JAN 2021 00:01

Patient Cloud Close Date & Time

07 JAN 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 13:55:17
Patient Cloud Open Date & Time	10 JAN 2021 00:01
Patient Cloud Close Date & Time	14 JAN 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 07:40:11

Patient Cloud Open Date & Time

17 JAN 2021 00:01

Patient Cloud Close Date & Time

21 JAN 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT	DAY 180
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	24 JAN 2021 00:01
Patient Cloud Close Date & Time	28 JAN 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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 type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	True
Chills	True
Cough	False
Shortness of breath	False
Difficulty breathing	False
Fatigue	False
Muscle aches	False
Body aches	False
Headache	False
New loss of taste	False
New loss of smell	False
Sore throat	False
Congestion	False
Runny nose	False
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message 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"/>
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	31 JAN 2021 12:04:07
Patient Cloud Open Date & Time	31 JAN 2021 00:01
PRODUCTION RELEASE (v12.003 EAB) (1725)	
143 of 2488	

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

04 FEB 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 07:16:10
Patient Cloud Open Date & Time	07 FEB 2021 00:01
Patient Cloud Close Date & Time	11 FEB 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	15 FEB 2021 14:13:55
Patient Cloud Open Date & Time	14 FEB 2021 00:01
Patient Cloud Close Date & Time	18 FEB 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 05:01:32

Patient Cloud Open Date & Time

21 FEB 2021 00:01

Patient Cloud Close Date & Time

25 FEB 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 05:08:57

Patient Cloud Open Date & Time

28 FEB 2021 00:01

Patient Cloud Close Date & Time

04 MAR 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 222

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

07 MAR 2021 12:54:27

Patient Cloud Open Date & Time

07 MAR 2021 00:01

Patient Cloud Close Date & Time

11 MAR 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 05:08:24
Patient Cloud Open Date & Time	14 MAR 2021 00:01
Patient Cloud Close Date & Time	18 MAR 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 05:40:49
Patient Cloud Open Date & Time	21 MAR 2021 00:01
Patient Cloud Close Date & Time	25 MAR 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 08:21:05

Patient Cloud Open Date & Time

28 MAR 2021 00:01

Patient Cloud Close Date & Time

01 APR 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 250

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

08 APR 2021 08:18:10

Patient Cloud Open Date & Time

04 APR 2021 00:01

Patient Cloud Close Date & Time

08 APR 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 07:38:33

Patient Cloud Open Date & Time

11 APR 2021 00:01

Patient Cloud Close Date & Time

15 APR 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 07:30:54

Patient Cloud Open Date & Time

18 APR 2021 00:01

Patient Cloud Close Date & Time

22 APR 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 05:31:52

Patient Cloud Open Date & Time

25 APR 2021 00:01

Patient Cloud Close Date & Time

29 APR 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 278

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

[Patient Cloud Close Date & Time](#)

06 MAY 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 285

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT	DAY 292
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

[Patient Cloud Close Date & Time](#)

20 MAY 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 299

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 306

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

03 JUN 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

10 JUN 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

[Patient Cloud Close Date & Time](#)

17 JUN 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

24 JUN 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

[Patient Cloud Close Date & Time](#)

01 JUL 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 348

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 355

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

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

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

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

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

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

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 362

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	29 JUL 2021 23:59
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US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 383

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

19 AUG 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 390

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

26 AUG 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

02 SEP 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 404

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

09 SEP 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 439

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 446

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 460

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

04 NOV 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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°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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

11 NOV 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 474

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT	DAY 488
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

[Patient Cloud Close Date & Time](#)

02 DEC 2021 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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="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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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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US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 516

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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
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Patient Cloud Close Date & Time	30 DEC 2021 23:59
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US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

06 JAN 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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°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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

[Patient Cloud Close Date & Time](#)

20 JAN 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 544

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

27 JAN 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 551

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JAN 2022 00:01

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03 FEB 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 FEB 2022 00:01

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10 FEB 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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17 FEB 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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°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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

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24 FEB 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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°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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

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27 FEB 2022 00:01

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03 MAR 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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[Patient Cloud Close Date & Time](#)

10 MAR 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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17 MAR 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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24 MAR 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

07 APR 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

14 APR 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 628

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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17 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

21 APR 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 635

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 642

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

05 MAY 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 656

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 670

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

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

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

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

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

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

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

09 JUN 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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="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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

[Patient Cloud Close Date & Time](#)

16 JUN 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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="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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

23 JUN 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT	DAY 698
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2022 00:01
Patient Cloud Close Date & Time	30 JUN 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 705

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

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

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

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

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

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

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUL 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 719

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUL 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 726

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUL 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 733

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

04 AUG 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

[Patient Cloud Close Date & Time](#)

01 SEP 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

[Patient Cloud Close Date & Time](#)

15 SEP 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

22 SEP 2022 23:59

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT	DAY 796
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:29:16

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 05:09:18

US3412067

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:28:55

Generated On: 09 Jun 2021 17:29:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412067

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:28:55

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 NOV 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412067

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 MAR 2021
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT4

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:09:27

Generated On: 09 Jun 2021 17:29:16

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) _____

US3412067

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

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.

US3412067

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

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

Collection date (dd MMM yyyy)	02 MAR 2021
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Collection time (00:00-23:59)	08:01 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	02 MAR 2021 08:01
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US3412067

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 29 MAR 2021

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

Comments PHONE NOT RINGING 29 MAR
2021. CONTACT MADE 30 MAR
2021.
If Contact Not Made, please provide Comments

US3412067

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:09:26

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412067

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412067

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:29:16

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"/>

US3412067

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:29:16

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412067

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:09:25

Generated On: 09 Jun 2021 17:29:16

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

Visit date (dd MMM yyyy)	2 MAR 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3412067

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:09:25

Generated On: 09 Jun 2021 17:29:16

Date of updated informed consent (dd MMM yyyy) 2 MAR 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) 2 MAR 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 _____

US3412067

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:09:25

Generated On: 09 Jun 2021 17:29:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 MAR 2021
Collection time (00:00-23:59)	08:01 (24 HR)
Collection date and time (derived)	2 MAR 2021 08:01

US3412067

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:09:25

Generated On: 09 Jun 2021 17:29:16

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	2 MAR 2021
Collection time (00:00 - 23:59)	08:03
Collection Date and Time (derived)	2 MAR 2021 08:03

US3412067

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:27:49

Generated On: 09 Jun 2021 17:29:16

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

AEID	USA-US061-2021-MRNA-1273-P30 1000008
Adverse event	POST-OP INFECTION
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)	02 FEB 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)	02 FEB 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

SUBJECT RETURNED SITES
VOICEMAIL AND STATED THAT
HE WAS IN HOSPITAL DUE TO
AN INFECTION FROM HIS BACK
SURGERY. SUBJECT HAD
ORIGINAL BACK SURGERY ON
05-JAN-2021. THIS WAS A
PLANNED PROCEDURE DUE TO
HIS OA OF THE BACK. SUBJECT
HAD A FOLLOW UP SURGERY
ON 08-JAN-2021 THAT WAS
ALSO PLANNED. HOWEVER
STARTING ON 02-FEB-2021
SUBJECT DEVELOPED A
POST-OP INFECTION THAT
HOSPITALIZED HIM ON THE
SAME DAY. SUBJECT IS BEING
TREATED WITH ANTI-BIOTICS
AND STILL CURRENTLY IN
HOSPITAL. SITE WILL REQUEST
MEDICAL RECORDS FOR
FURTHER INFORMATION.

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

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

AEID	USA-US061-2021-MRNA-1273-P30 1000008
Adverse event	PROGRESSIVE/WORSENING OSTEOARTHRITIS - BACK
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)	01 NOV 2020
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)	3 JAN 2021
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	
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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

PER PI'S INSTRUCTIONS THIS
WAS TO BE A SEPARATED SAE
FROM THE POST-OP WOUND
INFECTION AND BE WRITTEN
UP ON ITS OWN. SUBJECT HAD
A WORSENING OF THEIR
OSTEOARTHRITIS THAT
REQUIRED A SCHEDULED
BACK SURGERY ON
03-JAN-2021 AND THEN A
SECONDARY BACK SURGERY
ON 08-JAN-2021. SITE IS
REQUESTING MEDICAL
RECORDS FOR ADDITIONAL
INFORMATION.

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

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:31:51

Generated On: 09 Jun 2021 17:29:16

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

Yes ☒

No ☐

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

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication CYCLOBENZAPONE

Prophylaxis Yes ☐
No ☒

Indication NECK PAIN

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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 APR 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"/>

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication DICLOFENAC

Prophylaxis Yes ☐
No ☒

Indication OA

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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 2010	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication VENLAFAXINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY/DEPRESSION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication PIOGLITAZONE

Prophylaxis Yes ☐
No ☒

Indication T2DM

Dose per administration 45

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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 2007	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication TAMSULOSIN

Prophylaxis Yes ☐
No ☒

Indication BPH

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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 APR 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"/>

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication ATORVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HIGH CHOLESTEROL

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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)	15 APR 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"/>

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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 2010	
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"/>

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication VICTOZA

Prophylaxis Yes ☐
No ☒

Indication T2DM

Dose per administration 1.8

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2012	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication FLU VACCINE

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	Intramuscular	<input checked="" type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		05 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		05 NOV 2020
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"/>

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication CEFAZOLIN

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

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

EVERY 8 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY SIX HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		06 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 13 FEB 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"/>

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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) _____		
Start date completely unknown		True
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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) _____		
Start date completely unknown		True
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"/>

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration 750

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

EVERY 6 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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) _____		
Start date completely unknown		True
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication ROPINIROLE

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration 0.25

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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) _____		
Start date completely unknown		True
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication SENNOSIDEIDES-DOCUSATE

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration 8.6/50

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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) _____		
Start date completely unknown		True
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication GENERAL ENDOTRACHEAL ANESTHESIA

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	Intraocular	<input type="radio"/>
	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	PER HOSPITAL PROTOCOL	
Start date (dd MMM yyyy)	02 FEB 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	02 FEB 2021	
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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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)	26 JAN 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 FEB 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"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration 650

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

EVERY 4 HOURS AS NEEDED

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	06 FEB 2021	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="radio"/>	
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802 <input type="checkbox"/>	
	803 <input type="checkbox"/>	
	804 <input type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication HYDROMORPHONE (DILAUDID)

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration 0.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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 checked="" type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		26 JAN 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication LOVERSOL

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 26 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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 checked="" type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 26 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication PIPERACILLIN-TAZOBACTAM

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration 3.375

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 26 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input checked="" type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	26 JAN 2021	
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"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY HOUR HOUR

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		26 JAN 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication HEPARIN

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration 5000

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

EVERY 8 HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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)	26 JAN 2021	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		27 JAN 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"/>

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication ONDANSETRON

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

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

EVERY 6 HOURS AS NEEDED

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

PRODUCTION RELEASE (v12.003

393 of 2488

EAB) (1725)

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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)		02 FEB 2021
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 FEB 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"/>

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Name of Medication NOVOLOG

Prophylaxis Yes ☐
No ☒

Indication POST OP INFECTION

Dose per administration UNK

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

PER SLIDING SCALE

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

PRODUCTION RELEASE (v12.003

395 of 2488

EAB) (1725)

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

	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)	26 JAN 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 FEB 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"/>

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:31:51

Generated On: 09 Jun 2021 17:29:16

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 14:39:25

Generated On: 09 Jun 2021 17:29:16

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
05 JAN 2021	BACK SURGERY	Adverse Event	
08 JAN 2021	BACK SURGERY	Adverse Event	
02 FEB 2021	LUMBAR WOUND IRRIGATION AND DEBRIDEMENT	Adverse Event	
31 JAN 2021	MRI LUMBAR SPINE W/O CONTRAST	Adverse Event	
30 JAN 2021	XR CHEST AP PORTABLE	Adverse Event	
31 JAN 2021	CT LUMBAR SPINE WITHOUT CONTRAST	Adverse Event	

US3412067

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:29:16

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

US3412067

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:29:16

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 ☐

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 14:09:25

Generated On: 09 Jun 2021 17:29:16

SAEID	USA-US061-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 14:09:25

Generated On: 09 Jun 2021 17:29:16

SAEID	USA-US061-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	08/FEB/2021 11:02
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 14:09:25

Generated On: 09 Jun 2021 17:29:16

SAEID	USA-US061-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	18/FEB/2021 15:26
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

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 14:09:25

Generated On: 09 Jun 2021 17:29:16

SAEID	USA-US061-2021-MRNA-1273-P301000008
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	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)	3
Date of submission (Pre-filled from custom function)	12/APR/2021 13:56
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

US3412067 (Prod: New Horizons Clinical Research)

US3412067

Form: Participant Creation

Generated On: 09 Jun 2021 17:29:16

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'US3412067'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 14:34:38

US3412067

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Jul 2020 16:20:23

US3412067

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 14:34:39

US3412067

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[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 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	31 Jul 2020 16:20:23

US3412067

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'SCRN'	System	31 Jul 2020 16:20:23

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered (b) (6) 1959'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 14:34:40

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '60'	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'YEARS'	System	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '60'	System	31 Jul 2020 16:21:05

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Male (M)'	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'I'	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:29:16

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	31 Jul 2020 16:20:45

US3412067

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:16

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '31 Jul 2020'	Steven Anderson (b) (4)	31 Jul 2020 16:21:05

US3412067

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Jul 2020'	System	31 Jul 2020 16:21:05

US3412067

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2020'	System	31 Jul 2020 16:21:05

US3412067

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:16

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Amendment 1 (1)'	Steven Anderson (b) (4)	31 Jul 2020 16:21:05

US3412067

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Jul 2020 16:21:05

US3412067

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:16

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	31 Jul 2020 16:21:05

US3412067

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:16

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	31 Jul 2020 16:21:05

US3412067

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:16

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	31 Jul 2020 16:21:05

US3412067

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:16

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 14:34:39

US3412067

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:29:16

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'I'	System	31 Jul 2020 16:21:11

US3412067

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Jul 2020 16:21:11

US3412067

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:29:16

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User closed query 'Per CM, cyclobenzapone for neck pain - should neck pain be added to MedHx?' (Site from CRA).	(b) (4) (b) (4), (b) (6)	01 Oct 2020 23:19:48
Query 'Per CM, cyclobenzapone for neck pain - should neck pain be added to MedHx?' answered with 'added surgery to medical history ' (Site from CRA).	Jacob sekinger (b) (4) (b) (4)	30 Sep 2020 13:44:21
User opened query 'Per CM, cyclobenzapone for neck pain - should neck pain be added to MedHx?' (Site from CRA).	(b) (4), (b) (6)	21 Sep 2020 19:46:17
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	07 Aug 2020 13:08:55

US3412067

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Sleep apnoea syndrome, LLT: Sleep apnea - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:11:17
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:11:17
Data point term sent to Coder	System	07 Aug 2020 13:10:22
User entered 'Sleep Apnea'	Steven Anderson (b) (4)	07 Aug 2020 13:09:29

US3412067

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '31 Jul 2020'	Steven Anderson (b) (4)	07 Aug 2020 13:09:29

US3412067

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:09:29

US3412067

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:09:29

US3412067

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:09:29

US3412067

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:09:29

US3412067

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Jul 2020'	System	07 Aug 2020 13:09:29

US3412067

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2020'	System	07 Aug 2020 13:09:29

US3412067

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:09:29

US3412067

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:09:29

US3412067

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
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)	07 Aug 2020 13:11:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:11:16
Data point term sent to Coder	System	07 Aug 2020 13:10:20
User entered 'Hyperlipidemia'	Steven Anderson (b) (4)	07 Aug 2020 13:09:59

US3412067

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'un UNK 2010'	Steven Anderson (b) (4)	07 Aug 2020 13:09:59

US3412067

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:09:59

US3412067

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:09:59

US3412067

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:09:59

US3412067

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:09:59

US3412067

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Jan 2010'	System	07 Aug 2020 13:09:59

US3412067

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2010'	System	07 Aug 2020 13:09:59

US3412067

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:09:59

US3412067

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:09:59

US3412067

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
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)	07 Aug 2020 13:12:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:12:18
Data point term sent to Coder	System	07 Aug 2020 13:11:22
User entered 'Hypertension'	Steven Anderson (b) (4)	07 Aug 2020 13:10:24

US3412067

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'un UNK 2010'	Steven Anderson (b) (4)	07 Aug 2020 13:10:24

US3412067

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:10:24

US3412067

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:10:24

US3412067

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:10:24

US3412067

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:10:24

US3412067

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Jan 2010'	System	07 Aug 2020 13:10:24

US3412067

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2010'	System	07 Aug 2020 13:10:24

US3412067

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:10:24

US3412067

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:10:24

US3412067

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User coded data point as SOC: Reproductive system and breast disorders, HLGT: Prostatic disorders (excl infections and inflammations), HLT: Prostatic neoplasms and hypertrophy, PT: Benign prostatic hyperplasia, LLT: BPH - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:12:19
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:12:19
Data point term sent to Coder	System	07 Aug 2020 13:11:22
User entered 'BPH'	Steven Anderson (b) (4)	07 Aug 2020 13:10:53

US3412067

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'un Mar 2020'	Steven Anderson (b) (4)	07 Aug 2020 13:10:53

US3412067

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:10:53

US3412067

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:10:53

US3412067

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:10:53

US3412067

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:10:53

US3412067

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Mar 2020'	System	07 Aug 2020 13:10:53

US3412067

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2020'	System	07 Aug 2020 13:10:53

US3412067

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:10:53

US3412067

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:10:53

US3412067

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Generalised osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 00:53:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	25 Nov 2020 00:53:01
User closed query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	12 Oct 2020 18:22:01
' (Site from DM).		
Query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	Jacob sekinger (b) (4)	30 Sep 2020 13:40:10
' answered with 'updated.' (Site from DM).		
Data point term sent to Coder	System	30 Sep 2020 13:40:05
Coding entries removed.	Jacob sekinger (b) (4)	30 Sep 2020 13:40:03
User entered 'OSTEOARTHRITIS - bilateral knees, lower back, neck, hands, feet.' reason for change:	(b) (4)	
Data Entry Error	Jacob sekinger (b) (4)	30 Sep 2020 13:40:03
User opened query 'Per DM CLR: Please specify the location of OSTEOARTHRITIS. Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable.	(b) (4), (b) (6)	25 Sep 2020 16:22:09
' (Site from DM).		
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 13:12:18
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	07 Aug 2020 13:12:18
Data point term sent to Coder	System	07 Aug 2020 13:11:22

US3412067

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:16

[Condition](#)

Audit	User	Time (GMT)
User entered 'Osteoarthritis'	Steven Anderson (b) (4) (b) (4)	07 Aug 2020 13:11:19

US3412067

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'un UNK 2005'	Steven Anderson (b) (4)	07 Aug 2020 13:11:19

US3412067

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:11:19

US3412067

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:11:19

US3412067

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:11:19

US3412067

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:11:19

US3412067

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Jan 2005'	System	07 Aug 2020 13:11:19

US3412067

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2005'	System	07 Aug 2020 13:11:19

US3412067

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:11:19

US3412067

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:11:19

US3412067

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 2 diabetes mellitus, LLT: Type 2 diabetes mellitus - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:13:13
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:13:13
Data point term sent to Coder	System	07 Aug 2020 13:12:23
User entered 'Type 2 Diabetes'	Steven Anderson (b) (4)	07 Aug 2020 13:11:46

US3412067

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'un UNK 2010'	Steven Anderson (b) (4)	07 Aug 2020 13:11:46

US3412067

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:16

Start date completely unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:11:46

US3412067

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:11:46

US3412067

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:11:46

US3412067

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:11:46

US3412067

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Jan 2010'	System	07 Aug 2020 13:11:46

US3412067

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2010'	System	07 Aug 2020 13:11:46

US3412067

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:11:46

US3412067

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:11:46

US3412067

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:29:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User coded data point as SOC: Psychiatric disorders, HLT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:13:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:13:12
Data point term sent to Coder	System	07 Aug 2020 13:12:24
User entered 'Anxiety'	Steven Anderson (b) (4)	07 Aug 2020 13:12:12

US3412067

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'un UNK 2018'	Steven Anderson (b) (4)	07 Aug 2020 13:12:12

US3412067

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:12:12

US3412067

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:29:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:12:12

US3412067

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:12:12

US3412067

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:29:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:12:12

US3412067

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Jan 2018'	System	07 Aug 2020 13:12:12

US3412067

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2018'	System	07 Aug 2020 13:12:12

US3412067

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:12:12

US3412067

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:12:12

US3412067

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:29:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User coded data point as SOC: Psychiatric disorders, HLG: Depressed mood disorders and disturbances, HLT: Depressive disorders, PT: Depression, LLT: Depression - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:14:10
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	07 Aug 2020 13:14:10
Data point term sent to Coder	System	07 Aug 2020 13:13:25
User entered 'Depression'	Steven Anderson (b) (4)	07 Aug 2020 13:12:46

US3412067

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'un UNK 2018'	Steven Anderson (b) (4)	07 Aug 2020 13:12:46

US3412067

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:12:46

US3412067

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:29:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:12:46

US3412067

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:12:46

US3412067

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:29:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:12:46

US3412067

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Jan 2018'	System	07 Aug 2020 13:12:46

US3412067

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2018'	System	07 Aug 2020 13:12:46

US3412067

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:12:46

US3412067

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	07 Aug 2020 13:12:46

US3412067

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:29:16

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Nervous system, skull and spine therapeutic procedures, HLT: Spine and spinal cord therapeutic procedures, PT: Spinal fusion surgery, LLT: Fusion cervical spine - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	30 Sep 2020 15:39:26
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	30 Sep 2020 15:39:26
Data point term sent to Coder	System	30 Sep 2020 13:44:11
User entered 'neck surgery - cervical fusion'	Jacob sekinger (b) (4)	30 Sep 2020 13:43:58
	(b) (4)	

US3412067

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '15 Apr 2020'	Jacob sekinger (b) (4)	30 Sep 2020 13:43:58

US3412067

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Jacob sekinger (b) (4)	30 Sep 2020 13:43:58

US3412067

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:29:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Jacob sekinger (b) (4)	30 Sep 2020 13:43:58

US3412067

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '15 Apr 2020'	Jacob sekinger (b) (4)	30 Sep 2020 13:43:58

US3412067

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:29:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Jacob sekinger (b) (4)	30 Sep 2020 13:43:58

US3412067

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Apr 2020'	System	30 Sep 2020 13:43:58

US3412067

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2020'	System	30 Sep 2020 13:43:58

US3412067

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Apr 2020'	System	30 Sep 2020 13:43:58

US3412067

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2020'	System	30 Sep 2020 13:43:58

US3412067

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:29:16

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Knee operation, LLT: Knee operation - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 13:15:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Oct 2020 13:15:29
Data point term sent to Coder	System	06 Oct 2020 16:01:54
User entered 'right knee septic joint surgery'	Jacob sekinger (b) (4)	06 Oct 2020 16:01:52

US3412067

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'un UNK 2015'	Jacob sekinger (b) (4)	06 Oct 2020 16:01:52

US3412067

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Jacob sekinger (b) (4)	06 Oct 2020 16:01:52

US3412067

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:29:16

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Jacob sekinger (b) (4)	06 Oct 2020 16:01:52

US3412067

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'un UNK 2015'	Jacob sekinger (b) (4)	06 Oct 2020 16:01:52

US3412067

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:29:16

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Jacob sekinger (b) (4)	06 Oct 2020 16:01:52

US3412067

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Jan 2015'	System	06 Oct 2020 16:01:52

US3412067

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2015'	System	06 Oct 2020 16:01:52

US3412067

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'Jan 2015'	System	06 Oct 2020 16:01:52

US3412067

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '2015'	System	06 Oct 2020 16:01:52

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:15:38

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '31 Jul 2020'	Steven Anderson (b) (4)	07 Aug 2020 13:15:38

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '10:33'	Steven Anderson (b) (4)	07 Aug 2020 13:15:38

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '31 Jul 2020 10:33'	System	07 Aug 2020 13:15:38

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '174.0' cm	Steven Anderson (b) (4)	07 Aug 2020 13:15:38
DataPoint set to visible.	System	31 Jul 2020 16:21:11

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '92.9' kg	Steven Anderson (b) (4)	07 Aug 2020 13:15:38
DataPoint set to visible.	System	31 Jul 2020 16:21:11

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
Amendment Manager: User entered '30.68437'	System	16 Sep 2020 23:39:38
User entered '30.7'	System	07 Aug 2020 13:15:38
DataPoint set to visible.	System	31 Jul 2020 16:21:11

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'kg/m2'	System	07 Aug 2020 13:15:38
DataPoint set to visible.	System	31 Jul 2020 16:21:11

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Aug 2020 20:36:37
User entered '36.5' C	Myelene Asmar-Rios (b) (4)	07 Aug 2020 13:15:38
	Steven Anderson (b) (4)	

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty; reason for change Data Entry Error	(b) (4)	21 Aug 2020 15:09:59
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:15:38
	(b) (4)	

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:15:38

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Aug 2020 20:36:37
User entered '68'	Steven Anderson (b) (4)	07 Aug 2020 13:15:38

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'bpm'	System	07 Aug 2020 13:15:38

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Aug 2020 20:36:37
User entered '16'	Steven Anderson (b) (4)	07 Aug 2020 13:15:38

US3412067

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'breaths/min'	System	07 Aug 2020 13:15:38

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Folder: Screening

Form: Vital Signs

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Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Aug 2020 20:36:37
User entered '120'	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:15:38
	Steven Anderson (b) (4)	

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Folder: Screening

Form: Vital Signs

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'mmHg'	System	07 Aug 2020 13:15:38

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Folder: Screening

Form: Vital Signs

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Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	20 Aug 2020 20:36:37
User entered '70'	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:15:38
	Steven Anderson (b) (4)	

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'mmHg'	System	07 Aug 2020 13:15:38

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Folder: Screening

Form: Vital Signs

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[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10

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Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:15:56

US3412067

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
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 13:55:22
User entered '31 Jul 2020'	Steven Anderson (b) (4) (b) (4)	07 Aug 2020 13:15:56

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Lives with a essential worker'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 12:56:44
User entered '1'	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:17:16
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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Resides in Nursing Home or Assisted Living Facility

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '1' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 12:56:44
User entered '0'	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:17:16
	(b) (4)	

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Folder: Screening

Form: Risk of Exposure

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[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '0'	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:29:16

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:17:16

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Jul 2020 16:20:09

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '31 Jul 2020'	Steven Anderson (b) (4)	31 Jul 2020 16:20:09

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	31 Jul 2020 16:20:09

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'VISIT1'	System	31 Jul 2020 16:20:09

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '31 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 16:04:24

US3412067

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:16

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:29:14
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:29:14
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	31 Jul 2020 16:04:24
User entered '142425' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 16:04:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	31 Jul 2020 16:04:24

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'No (N)'	Steven Anderson (b) (4)	31 Jul 2020 16:19:53

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'No (N)'	Steven Anderson (b) (4)	31 Jul 2020 16:19:53

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'No (N)'	Steven Anderson (b) (4)	31 Jul 2020 16:19:53

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:16

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Jul 2020 16:19:53

US3412067

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:29:16

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'No (N)'	Steven Anderson (b) (4)	31 Jul 2020 16:19:53

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:16

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	07 Aug 2020 13:19:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 20:38:08
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:19:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '31 Jul 2020' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 20:38:08
User entered empty.	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:19:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '10:33' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 20:38:08
User entered empty.	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:19:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered '31 Jul 2020 10:33'	System	20 Aug 2020 20:38:08
User entered empty.	System	07 Aug 2020 13:19:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '36.5' C reason for change: Data Entry Error	(b) (4)	20 Aug 2020 20:38:08
User entered empty.	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:19:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 20:38:08
User entered empty.	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:19:09
	(b) (4)	

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '68' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 20:38:08
User entered empty.	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:19:09
	(b) (4)	

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'bpm'	System	20 Aug 2020 20:38:08
User entered empty.	System	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '16' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 20:38:08
User entered empty.	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:19:09
	(b) (4)	

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'breaths/min'	System	20 Aug 2020 20:38:08
User entered empty.	System	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '120' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 20:38:08
User entered empty.	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:19:09
	(b) (4)	

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'mmHg'	System	20 Aug 2020 20:38:08
User entered empty.	System	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '70' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 20:38:08
User entered empty.	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:19:09
	(b) (4)	

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'mmHg'	System	20 Aug 2020 20:38:08
User entered empty.	System	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:16

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:29:16

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '31 Jul 2020'	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4) (b) (4), (b) (6)	18 Aug 2020 05:38:21
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' answered with 'Per protocol vital signs only need to be >30 minutes post dose' (Site from System).	Steven Anderson (b) (4) (b) (4)	07 Aug 2020 13:19:37
User opened query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		07 Aug 2020 13:19:09
User entered '12:58'	Steven Anderson (b) (4) (b) (4)	07 Aug 2020 13:19:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered '31 Jul 2020 12:58'	System	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '97.0' F	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '70'	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'bpm'	System	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '14'	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'breaths/min'	System	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '120'	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'mmHg'	System	07 Aug 2020 13:19:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '62'	Steven Anderson (b) (4)	07 Aug 2020 13:19:09

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'mmHg'	System	07 Aug 2020 13:19:09

US3412067

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:19:42

US3412067

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:19:42

US3412067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Jul 2020 16:22:15

US3412067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	31 Jul 2020 16:22:15

US3412067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	31 Jul 2020 16:22:15

US3412067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'MRNA-1273 OR PLACEBO'	System	31 Jul 2020 16:22:15

US3412067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '31 Jul 2020'	Steven Anderson (b) (4)	31 Jul 2020 16:22:15

US3412067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '12:10'	Steven Anderson (b) (4)	31 Jul 2020 16:22:15

US3412067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered '31 Jul 2020 12:10'	System	31 Jul 2020 16:22:15

US3412067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	31 Jul 2020 16:22:15

US3412067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'ONCE'	System	31 Jul 2020 16:22:15

US3412067

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'INTRAMUSCULAR'	System	31 Jul 2020 16:22:15

US3412067

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:20:22

US3412067

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '31 Jul 2020'	Steven Anderson (b) (4)	07 Aug 2020 13:20:22

US3412067

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '11:12'	Steven Anderson (b) (4)	07 Aug 2020 13:20:22

US3412067

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered '31 Jul 2020 11:12'	System	07 Aug 2020 13:20:22

US3412067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:29:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '31 Jul 2020'	Steven Anderson (b) (4)	07 Aug 2020 13:20:39

US3412067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	07 Aug 2020 13:20:39

US3412067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:20:39

US3412067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '11:00'	Steven Anderson (b) (4)	07 Aug 2020 13:20:39

US3412067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User entered '31 Jul 2020 11:00'	System	07 Aug 2020 13:20:39

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	07 Aug 2020 13:20:39

US3412067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
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	07 Aug 2020 13:20:46
User entered 'No (N)' reason for change: Data Entry Error	System	07 Aug 2020 13:20:46
User opened query 'Data is required. Please complete.' (Site from System).	Steven Anderson (b) (4)	07 Aug 2020 13:20:46
User entered empty.	(b) (4)	
	System	07 Aug 2020 13:20:39
	Steven Anderson (b) (4)	07 Aug 2020 13:20:39
	(b) (4)	

US3412067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 13:20:39

US3412067

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User entered empty.	System	07 Aug 2020 13:20:39

US3412067

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 13:20:54

US3412067

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User entered 'I'	System	07 Aug 2020 13:20:54

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:07:04', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7808f9ca-3e06-425e-8417-0a97d30be686'	System	31 Jul 2020 17:07:49
User entered 'Yes (Y)'	System	31 Jul 2020 17:07:49

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:07:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7808f9ca-3e06-425e-8417-0a97d30be686'	System	31 Jul 2020 17:07:49
User entered '97.0'	System	31 Jul 2020 17:07:49

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:07:29', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7808f9ca-3e06-425e-8417-0a97d30be686'	System	31 Jul 2020 17:07:49
User entered 'No (N)'	System	31 Jul 2020 17:07:49

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:07:45', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7808f9ca-3e06-425e-8417-0a97d30be686'	System	31 Jul 2020 17:07:49
User entered '31 Jul 2020 13:07'	System	31 Jul 2020 17:07:49

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Jul 2020 12:30'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Jul 2020 15:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:14:37', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83cfc89d-4e32-4665-b6ac-e972015e8ea8'	System	31 Jul 2020 22:15:49
User entered 'Yes (Y)'	System	31 Jul 2020 22:15:49

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:14:59', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83cfc89d-4e32-4665-b6ac-e972015e8ea8'	System	31 Jul 2020 22:15:49
User entered '97.4'	System	31 Jul 2020 22:15:49

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:15:07', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83cfc89d-4e32-4665-b6ac-e972015e8ea8'	System	31 Jul 2020 22:15:49
User entered 'No (N)'	System	31 Jul 2020 22:15:49

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:15:45', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83cfc89d-4e32-4665-b6ac-e972015ebea8'	System	31 Jul 2020 22:15:49
User entered '31 Jul 2020 18:15'	System	31 Jul 2020 22:15:49

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Jul 2020 15:55'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 2'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:33:29', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7690d464-ec96-44f4-bda2-3629f9d0a961'	System	01 Aug 2020 21:34:03
User entered 'Yes (Y)'	System	01 Aug 2020 21:34:03

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:33:42', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7690d464-ec96-44f4-bda2-3629f9d0a961'	System	01 Aug 2020 21:34:03
User entered '97.5'	System	01 Aug 2020 21:34:03

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:33:47', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7690d464-ec96-44f4-bda2-3629f9d0a961'	System	01 Aug 2020 21:34:03
User entered 'No (N)'	System	01 Aug 2020 21:34:03

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:34:03', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7690d464-ec96-44f4-bda2-3629f9d0a961'	System	01 Aug 2020 21:34:03
User entered '01 Aug 2020 17:34'	System	01 Aug 2020 21:34:03

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 3'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:47:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1ebdac98-2fdf-40c1-bfb6-cec04114c27f'	System	02 Aug 2020 21:47:41
User entered 'Yes (Y)'	System	02 Aug 2020 21:47:41

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:47:24', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1ebdac98-2fdf-40c1-bfb6-cec04114c27f'	System	02 Aug 2020 21:47:41
User entered '97.2'	System	02 Aug 2020 21:47:41

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:47:29', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1ebdac98-2fdf-40c1-bfb6-cec04114c27f'	System	02 Aug 2020 21:47:41
User entered 'No (N)'	System	02 Aug 2020 21:47:41

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:47:38', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1ebdac98-2fdf-40c1-bfb6-cec04114c27f'	System	02 Aug 2020 21:47:41
User entered '02 Aug 2020 17:47'	System	02 Aug 2020 21:47:41

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 4'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:43:01', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a9e0f907-6306-44d5-8d8b-afceacd0fd49'	System	04 Aug 2020 09:43:27
User entered 'Yes (Y)'	System	04 Aug 2020 09:43:27

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:43:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a9e0f907-6306-44d5-8d8b-afceacd0fd49'	System	04 Aug 2020 09:43:27
User entered '97.4'	System	04 Aug 2020 09:43:27

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:43:19', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a9e0f907-6306-44d5-8d8b-afceacd0fd49'	System	04 Aug 2020 09:43:27
User entered 'No (N)'	System	04 Aug 2020 09:43:27

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:43:24', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a9e0f907-6306-44d5-8d8b-afceacd0fd49'	System	04 Aug 2020 09:43:27
User entered '04 Aug 2020 05:43'	System	04 Aug 2020 09:43:27

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 5'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:43:28', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3ac07138-7c9f-4de9-b9b9-dbd9cefd2ee4'	System	04 Aug 2020 21:43:59
User entered 'Yes (Y)'	System	04 Aug 2020 21:43:59

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:43:40', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3ac07138-7c9f-4de9-b9b9-dbd9cefd2ee4' User entered '97.2'	System	04 Aug 2020 21:43:59
	System	04 Aug 2020 21:43:59

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:43:45', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3ac07138-7c9f-4de9-b9b9-dbd9cefd2ee4'	System	04 Aug 2020 21:43:59
User entered 'No (N)'	System	04 Aug 2020 21:43:59

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:43:55', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3ac07138-7c9f-4de9-b9b9-dbd9cefd2ee4'	System	04 Aug 2020 21:43:59
User entered '04 Aug 2020 17:43'	System	04 Aug 2020 21:43:59

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 6'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:26:09', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'efc143ba-073b-4fdd-89ff-3e2a5b28c804'	System	05 Aug 2020 23:26:32
User entered 'Yes (Y)'	System	05 Aug 2020 23:26:32

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:26:17', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'efc143ba-073b-4fdd-89ff-3e2a5b28c804'	System	05 Aug 2020 23:26:32
User entered '97.3'	System	05 Aug 2020 23:26:32

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:26:23', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'efc143ba-073b-4fdd-89ff-3e2a5b28c804'	System	05 Aug 2020 23:26:32
User entered 'No (N)'	System	05 Aug 2020 23:26:32

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:26:29', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'efc143ba-073b-4fdd-89ff-3e2a5b28c804'	System	05 Aug 2020 23:26:32
User entered '05 Aug 2020 19:26'	System	05 Aug 2020 23:26:32

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 7'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:07:59', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3ac1d200-302b-4543-9f1d-e01d4342735f'	System	06 Aug 2020 22:08:24
User entered 'Yes (Y)'	System	06 Aug 2020 22:08:24

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:08:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3ac1d200-302b-4543-9f1d-e01d4342735f'	System	06 Aug 2020 22:08:24
User entered '97.3'	System	06 Aug 2020 22:08:24

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:08:15', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3ac1d200-302b-4543-9f1d-e01d4342735f'	System	06 Aug 2020 22:08:24
User entered 'No (N)'	System	06 Aug 2020 22:08:24

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:08:20', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3ac1d200-302b-4543-9f1d-e01d4342735f'	System	06 Aug 2020 22:08:24
User entered '06 Aug 2020 18:08'	System	06 Aug 2020 22:08:24

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:08:04', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '093eb5ee-c2e2-4fd7-bd53-1ba3216b2e6d'	System	31 Jul 2020 17:08:37
User entered 'None (1)'	System	31 Jul 2020 17:08:37

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:08:07', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '093eb5ee-c2e2-4fd7-bd53-1ba3216b2e6d'	System	31 Jul 2020 17:08:37
User entered 'No (N)'	System	31 Jul 2020 17:08:37

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:08:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '093eb5ee-c2e2-4fd7-bd53-1ba3216b2e6d'	System	31 Jul 2020 17:08:37
User entered 'No (N)'	System	31 Jul 2020 17:08:37

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:08:29', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '093eb5ee-c2e2-4fd7-bd53-1ba3216b2e6d'	System	31 Jul 2020 17:08:37
User entered 'None (1)'	System	31 Jul 2020 17:08:37

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:08:34', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '093eb5ee-c2e2-4fd7-bd53-1ba3216b2e6d'	System	31 Jul 2020 17:08:37
User entered '31 Jul 2020 13:08'	System	31 Jul 2020 17:08:37

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Jul 2020 12:30'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Jul 2020 15:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:16:09', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b657c6bb-3dee-411e-a6b0-275a38c521a5'	System	31 Jul 2020 22:17:01
User entered 'None (1)'	System	31 Jul 2020 22:17:01

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:16:15', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b657c6bb-3dee-411e-a6b0-275a38c521a5'	System	31 Jul 2020 22:17:01
User entered 'No (N)'	System	31 Jul 2020 22:17:01

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:16:20', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b657c6bb-3dee-411e-a6b0-275a38c521a5'	System	31 Jul 2020 22:17:01
User entered 'No (N)'	System	31 Jul 2020 22:17:01

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:16:43', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b657c6bb-3dee-411e-a6b0-275a38c521a5'	System	31 Jul 2020 22:17:01
User entered 'None (1)'	System	31 Jul 2020 22:17:01

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:16:58', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b657c6bb-3dee-411e-a6b0-275a38c521a5'	System	31 Jul 2020 22:17:01
User entered '31 Jul 2020 18:16'	System	31 Jul 2020 22:17:01

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Jul 2020 15:55'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 2'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:34:27', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3aa01cd1-3fd8-478f-aa8a-1996ccc58c1f'	System	01 Aug 2020 21:35:00
User entered 'Does not interfere with activity (2)'	System	01 Aug 2020 21:35:00

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:34:32', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3aa01cd1-3fd8-478f-aa8a-1996ccc58c1f'	System	01 Aug 2020 21:35:00
User entered 'No (N)'	System	01 Aug 2020 21:35:00

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:34:36', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3aa01cd1-3fd8-478f-aa8a-1996ccc58c1f'	System	01 Aug 2020 21:35:00
User entered 'No (N)'	System	01 Aug 2020 21:35:00

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:34:51', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3aa01cd1-3fd8-478f-aa8a-1996ccc58c1f'	System	01 Aug 2020 21:35:00
User entered 'None (1)'	System	01 Aug 2020 21:35:00

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:34:59', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3aa01cd1-3fd8-478f-aa8a-1996ccc58c1f'	System	01 Aug 2020 21:35:00
User entered '01 Aug 2020 17:34'	System	01 Aug 2020 21:35:00

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 3'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:48:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '941ae334-5707-4ef0-8e2f-b9c2c36460e9'	System	02 Aug 2020 21:48:33
User entered 'None (1)'	System	02 Aug 2020 21:48:33

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:48:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '941ae334-5707-4ef0-8e2f-b9c2c36460e9'	System	02 Aug 2020 21:48:33
User entered 'No (N)'	System	02 Aug 2020 21:48:33

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:48:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '941ae334-5707-4ef0-8e2f-b9c2c36460e9'	System	02 Aug 2020 21:48:33
User entered 'No (N)'	System	02 Aug 2020 21:48:33

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:48:25', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '941ae334-5707-4ef0-8e2f-b9c2c36460e9'	System	02 Aug 2020 21:48:33
User entered 'None (1)'	System	02 Aug 2020 21:48:33

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:48:29', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '941ae334-5707-4ef0-8e2f-b9c2c36460e9'	System	02 Aug 2020 21:48:33
User entered '02 Aug 2020 17:48'	System	02 Aug 2020 21:48:33

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 4'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:43:29', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9f729533-cece-4823-8817-74fd414e0a4a'	System	04 Aug 2020 09:43:58
User entered 'None (1)'	System	04 Aug 2020 09:43:58

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:43:35', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9f729533-cece-4823-8817-74fd414e0a4a'	System	04 Aug 2020 09:43:58
User entered 'No (N)'	System	04 Aug 2020 09:43:58

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:43:39', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9f729533-cece-4823-8817-74fd414e0a4a'	System	04 Aug 2020 09:43:58
User entered 'No (N)'	System	04 Aug 2020 09:43:58

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:43:47', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9f729533-cece-4823-8817-74fd414e0a4a'	System	04 Aug 2020 09:43:58
User entered 'None (1)'	System	04 Aug 2020 09:43:58

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:43:54', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9f729533-cece-4823-8817-74fd414e0a4a'	System	04 Aug 2020 09:43:58
User entered '04 Aug 2020 05:43'	System	04 Aug 2020 09:43:58

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 5'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:44:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '43a11887-f086-4dcb-8406-9e389c215894'	System	04 Aug 2020 21:44:47
User entered 'None (1)'	System	04 Aug 2020 21:44:47

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:44:18', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '43a11887-f086-4dcb-8406-9e389c215894'	System	04 Aug 2020 21:44:47
User entered 'No (N)'	System	04 Aug 2020 21:44:47

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:44:24', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '43a11887-f086-4dcb-8406-9e389c215894'	System	04 Aug 2020 21:44:47
User entered 'No (N)'	System	04 Aug 2020 21:44:47

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:44:37', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '43a11887-f086-4dcb-8406-9e389c215894'	System	04 Aug 2020 21:44:47
User entered 'None (1)'	System	04 Aug 2020 21:44:47

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:44:46', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '43a11887-f086-4dcb-8406-9e389c215894'	System	04 Aug 2020 21:44:47
User entered '04 Aug 2020 17:44'	System	04 Aug 2020 21:44:47

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 6'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:26:42', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '81549098-177d-4051-ad62-38765a9963b4'	System	05 Aug 2020 23:27:14
User entered 'None (1)'	System	05 Aug 2020 23:27:14

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:26:51', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '81549098-177d-4051-ad62-38765a9963b4'	System	05 Aug 2020 23:27:14
User entered 'No (N)'	System	05 Aug 2020 23:27:14

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:26:55', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '81549098-177d-4051-ad62-38765a9963b4'	System	05 Aug 2020 23:27:14
User entered 'No (N)'	System	05 Aug 2020 23:27:14

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:27:05', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '81549098-177d-4051-ad62-38765a9963b4'	System	05 Aug 2020 23:27:14
User entered 'None (1)'	System	05 Aug 2020 23:27:14

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:27:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '81549098-177d-4051-ad62-38765a9963b4'	System	05 Aug 2020 23:27:14
User entered '05 Aug 2020 19:27'	System	05 Aug 2020 23:27:14

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 7'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:08:26', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3e7b1fa6-dada-4ae5-a518-b4ce20573c74'	System	06 Aug 2020 22:09:13
User entered 'None (1)'	System	06 Aug 2020 22:09:13

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:08:30', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3e7b1fa6-dada-4ae5-a518-b4ce20573c74'	System	06 Aug 2020 22:09:13
User entered 'No (N)'	System	06 Aug 2020 22:09:13

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:08:33', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3e7b1fa6-dada-4ae5-a518-b4ce20573c74'	System	06 Aug 2020 22:09:13
User entered 'No (N)'	System	06 Aug 2020 22:09:13

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:09:01', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3e7b1fa6-dada-4ae5-a518-b4ce20573c74'	System	06 Aug 2020 22:09:13
User entered 'None (1)'	System	06 Aug 2020 22:09:13

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:09:06', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '3e7b1fa6-dada-4ae5-a518-b4ce20573c74'	System	06 Aug 2020 22:09:13
User entered '06 Aug 2020 18:09'	System	06 Aug 2020 22:09:13

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:08:48', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd6aaa720-6b26-4c87-b0d2-86636b2166d8'	System	31 Jul 2020 17:09:46
User entered 'None (0)'	System	31 Jul 2020 17:09:46

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:09:04', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd6aaa720-6b26-4c87-b0d2-86636b2166d8'	System	31 Jul 2020 17:09:46
User entered 'None (0)'	System	31 Jul 2020 17:09:46

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:09:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd6aaa720-6b26-4c87-b0d2-86636b2166d8'	System	31 Jul 2020 17:09:46
User entered 'None (0)'	System	31 Jul 2020 17:09:46

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:09:23', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd6aaa720-6b26-4c87-b0d2-86636b2166d8'	System	31 Jul 2020 17:09:46
User entered 'None (0)'	System	31 Jul 2020 17:09:46

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:09:26', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd6aaa720-6b26-4c87-b0d2-86636b2166d8'	System	31 Jul 2020 17:09:46
User entered 'None (0)'	System	31 Jul 2020 17:09:46

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:09:29', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd6aaa720-6b26-4c87-b0d2-86636b2166d8'	System	31 Jul 2020 17:09:46
User entered 'None (0)'	System	31 Jul 2020 17:09:46

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:09:37', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd6aaa720-6b26-4c87-b0d2-86636b2166d8'	System	31 Jul 2020 17:09:46
User entered 'No (N)'	System	31 Jul 2020 17:09:46

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T13:09:41', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd6aaa720-6b26-4c87-b0d2-86636b2166d8'	System	31 Jul 2020 17:09:46
User entered '31 Jul 2020 13:09'	System	31 Jul 2020 17:09:46

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Jul 2020 12:30'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Jul 2020 15:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 1, after vaccination (at home)'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:17:07', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '6e5d09f4-74e6-4ba7-ab5a-60d45c4bb07c'	System	31 Jul 2020 22:18:27
User entered 'None (0)'	System	31 Jul 2020 22:18:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:17:22', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '6e5d09f4-74e6-4ba7-ab5a-60d45c4bb07c'	System	31 Jul 2020 22:18:27
User entered 'None (0)'	System	31 Jul 2020 22:18:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:17:43', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '6e5d09f4-74e6-4ba7-ab5a-60d45c4bb07c'	System	31 Jul 2020 22:18:27
User entered 'None (0)'	System	31 Jul 2020 22:18:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:17:52', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '6e5d09f4-74e6-4ba7-ab5a-60d45c4bb07c'	System	31 Jul 2020 22:18:27
User entered 'None (0)'	System	31 Jul 2020 22:18:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:17:58', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '6e5d09f4-74e6-4ba7-ab5a-60d45c4bb07c'	System	31 Jul 2020 22:18:27
User entered 'None (0)'	System	31 Jul 2020 22:18:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:18:02', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '6e5d09f4-74e6-4ba7-ab5a-60d45c4bb07c'	System	31 Jul 2020 22:18:27
User entered 'None (0)'	System	31 Jul 2020 22:18:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:18:09', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '6e5d09f4-74e6-4ba7-ab5a-60d45c4bb07c'	System	31 Jul 2020 22:18:27
User entered 'No (N)'	System	31 Jul 2020 22:18:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-07-31T18:18:26', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '6e5d09f4-74e6-4ba7-ab5a-60d45c4bb07c'	System	31 Jul 2020 22:18:27
User entered '31 Jul 2020 18:18'	System	31 Jul 2020 22:18:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Jul 2020 15:55'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 2'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:35:05', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '29b291cc-ce99-47f3-8d85-d0d715e57d7a'	System	01 Aug 2020 21:35:34
User entered 'None (0)'	System	01 Aug 2020 21:35:34

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:35:09', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '29b291cc-ce99-47f3-8d85-d0d715e57d7a'	System	01 Aug 2020 21:35:34
User entered 'None (0)'	System	01 Aug 2020 21:35:34

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:35:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '29b291cc-ce99-47f3-8d85-d0d715e57d7a'	System	01 Aug 2020 21:35:34
User entered 'None (0)'	System	01 Aug 2020 21:35:34

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:35:17', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '29b291cc-ce99-47f3-8d85-d0d715e57d7a'	System	01 Aug 2020 21:35:34
User entered 'None (0)'	System	01 Aug 2020 21:35:34

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:35:20', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '29b291cc-ce99-47f3-8d85-d0d715e57d7a'	System	01 Aug 2020 21:35:34
User entered 'None (0)'	System	01 Aug 2020 21:35:34

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:35:23', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '29b291cc-ce99-47f3-8d85-d0d715e57d7a'	System	01 Aug 2020 21:35:34
User entered 'None (0)'	System	01 Aug 2020 21:35:34

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:35:26', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '29b291cc-ce99-47f3-8d85-d0d715e57d7a'	System	01 Aug 2020 21:35:34
User entered 'No (N)'	System	01 Aug 2020 21:35:34

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-01T17:35:33', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '29b291cc-ce99-47f3-8d85-d0d715e57d7a'	System	01 Aug 2020 21:35:34
User entered '01 Aug 2020 17:35'	System	01 Aug 2020 21:35:34

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 3'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:48:35', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '08a7797b-b5ce-4e60-a873-c04be79d5efc'	System	02 Aug 2020 21:49:27
User entered 'None (0)'	System	02 Aug 2020 21:49:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:48:38', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '08a7797b-b5ce-4e60-a873-c04be79d5efc'	System	02 Aug 2020 21:49:27
User entered 'None (0)'	System	02 Aug 2020 21:49:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:48:41', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '08a7797b-b5ce-4e60-a873-c04be79d5efc'	System	02 Aug 2020 21:49:27
User entered 'None (0)'	System	02 Aug 2020 21:49:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:48:45', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '08a7797b-b5ce-4e60-a873-c04be79d5efc'	System	02 Aug 2020 21:49:27
User entered 'None (0)'	System	02 Aug 2020 21:49:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:48:48', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '08a7797b-b5ce-4e60-a873-c04be79d5efc'	System	02 Aug 2020 21:49:27
User entered 'None (0)'	System	02 Aug 2020 21:49:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:48:53', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '08a7797b-b5ce-4e60-a873-c04be79d5efc'	System	02 Aug 2020 21:49:27
User entered 'None (0)'	System	02 Aug 2020 21:49:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:49:09', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '08a7797b-b5ce-4e60-a873-c04be79d5efc'	System	02 Aug 2020 21:49:27
User entered 'No (N)'	System	02 Aug 2020 21:49:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-02T17:49:21', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '08a7797b-b5ce-4e60-a873-c04be79d5efc'	System	02 Aug 2020 21:49:27
User entered '02 Aug 2020 17:49'	System	02 Aug 2020 21:49:27

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 4'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:43:59', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ea506185-296a-43f4-8fa8-224c9e4f2449'	System	04 Aug 2020 09:44:29
User entered 'None (0)'	System	04 Aug 2020 09:44:29

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:44:02', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ea506185-296a-43f4-8fa8-224c9e4f2449'	System	04 Aug 2020 09:44:29
User entered 'None (0)'	System	04 Aug 2020 09:44:29

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:44:06', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ea506185-296a-43f4-8fa8-224c9e4f2449'	System	04 Aug 2020 09:44:29
User entered 'None (0)'	System	04 Aug 2020 09:44:29

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:44:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ea506185-296a-43f4-8fa8-224c9e4f2449'	System	04 Aug 2020 09:44:29
User entered 'None (0)'	System	04 Aug 2020 09:44:29

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:44:13', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ea506185-296a-43f4-8fa8-224c9e4f2449'	System	04 Aug 2020 09:44:29
User entered 'None (0)'	System	04 Aug 2020 09:44:29

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:44:16', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ea506185-296a-43f4-8fa8-224c9e4f2449'	System	04 Aug 2020 09:44:29
User entered 'None (0)'	System	04 Aug 2020 09:44:29

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:44:21', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ea506185-296a-43f4-8fa8-224c9e4f2449'	System	04 Aug 2020 09:44:29
User entered 'No (N)'	System	04 Aug 2020 09:44:29

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T05:44:25', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ea506185-296a-43f4-8fa8-224c9e4f2449'	System	04 Aug 2020 09:44:29
User entered '04 Aug 2020 05:44'	System	04 Aug 2020 09:44:29

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '04 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 5'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:44:51', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f12f23a6-1d66-490d-9988-e3a1262a066e'	System	04 Aug 2020 21:45:24
User entered 'None (0)'	System	04 Aug 2020 21:45:24

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:44:54', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f12f23a6-1d66-490d-9988-e3a1262a066e'	System	04 Aug 2020 21:45:24
User entered 'None (0)'	System	04 Aug 2020 21:45:24

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:44:57', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f12f23a6-1d66-490d-9988-e3a1262a066e'	System	04 Aug 2020 21:45:24
User entered 'None (0)'	System	04 Aug 2020 21:45:24

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:45:04', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f12f23a6-1d66-490d-9988-e3a1262a066e'	System	04 Aug 2020 21:45:24
User entered 'None (0)'	System	04 Aug 2020 21:45:24

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:45:07', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f12f23a6-1d66-490d-9988-e3a1262a066e'	System	04 Aug 2020 21:45:24
User entered 'None (0)'	System	04 Aug 2020 21:45:24

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:45:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f12f23a6-1d66-490d-9988-e3a1262a066e'	System	04 Aug 2020 21:45:24
User entered 'None (0)'	System	04 Aug 2020 21:45:24

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:45:16', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f12f23a6-1d66-490d-9988-e3a1262a066e'	System	04 Aug 2020 21:45:24
User entered 'No (N)'	System	04 Aug 2020 21:45:24

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-04T17:45:23', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f12f23a6-1d66-490d-9988-e3a1262a066e'	System	04 Aug 2020 21:45:24
User entered '04 Aug 2020 17:45'	System	04 Aug 2020 21:45:24

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '04 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '05 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 6'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:27:19', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '01886cf8-6953-499f-b5c2-bc3208884583'	System	05 Aug 2020 23:28:01
User entered 'None (0)'	System	05 Aug 2020 23:28:01

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:27:22', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '01886cf8-6953-499f-b5c2-bc3208884583'	System	05 Aug 2020 23:28:01
User entered 'None (0)'	System	05 Aug 2020 23:28:01

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:27:31', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '01886cf8-6953-499f-b5c2-bc3208884583'	System	05 Aug 2020 23:28:01
User entered 'None (0)'	System	05 Aug 2020 23:28:01

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:27:39', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '01886cf8-6953-499f-b5c2-bc3208884583'	System	05 Aug 2020 23:28:01
User entered 'None (0)'	System	05 Aug 2020 23:28:01

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:27:42', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '01886cf8-6953-499f-b5c2-bc3208884583'	System	05 Aug 2020 23:28:01
User entered 'None (0)'	System	05 Aug 2020 23:28:01

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:27:46', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '01886cf8-6953-499f-b5c2-bc3208884583'	System	05 Aug 2020 23:28:01
User entered 'None (0)'	System	05 Aug 2020 23:28:01

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:27:51', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '01886cf8-6953-499f-b5c2-bc3208884583'	System	05 Aug 2020 23:28:01
User entered 'No (N)'	System	05 Aug 2020 23:28:01

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-05T19:27:57', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '01886cf8-6953-499f-b5c2-bc3208884583'	System	05 Aug 2020 23:28:01
User entered '05 Aug 2020 19:27'	System	05 Aug 2020 23:28:01

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '05 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '06 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 7'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:09:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b64ffd59-4489-49b0-a941-d3b10b8a200d'	System	06 Aug 2020 22:09:58
User entered 'None (0)'	System	06 Aug 2020 22:09:58

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:09:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b64ffd59-4489-49b0-a941-d3b10b8a200d'	System	06 Aug 2020 22:09:58
User entered 'None (0)'	System	06 Aug 2020 22:09:58

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:09:24', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b64ffd59-4489-49b0-a941-d3b10b8a200d'	System	06 Aug 2020 22:09:58
User entered 'None (0)'	System	06 Aug 2020 22:09:58

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:09:32', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b64ffd59-4489-49b0-a941-d3b10b8a200d'	System	06 Aug 2020 22:09:58
User entered 'None (0)'	System	06 Aug 2020 22:09:58

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:09:41', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b64ffd59-4489-49b0-a941-d3b10b8a200d'	System	06 Aug 2020 22:09:58
User entered 'None (0)'	System	06 Aug 2020 22:09:58

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:09:44', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b64ffd59-4489-49b0-a941-d3b10b8a200d'	System	06 Aug 2020 22:09:58
User entered 'None (0)'	System	06 Aug 2020 22:09:58

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:09:48', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b64ffd59-4489-49b0-a941-d3b10b8a200d'	System	06 Aug 2020 22:09:58
User entered 'No (N)'	System	06 Aug 2020 22:09:58

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-06T18:09:52', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b64ffd59-4489-49b0-a941-d3b10b8a200d'	System	06 Aug 2020 22:09:58
User entered '06 Aug 2020 18:09'	System	06 Aug 2020 22:09:58

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '06 Aug 2020 12:00'	System	31 Jul 2020 16:22:15

US3412067

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '07 Aug 2020 11:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 19:51:23

US3412067

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '07 Aug 2020'	Steven Anderson (b) (4)	07 Aug 2020 19:51:23

US3412067

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	07 Aug 2020 19:51:23

US3412067

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	07 Aug 2020 19:51:23

US3412067

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	07 Aug 2020 19:51:35

US3412067

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User entered 'I'	System	07 Aug 2020 19:51:35

US3412067

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Aug 2020 14:51:42

US3412067

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '14 Aug 2020'	Steven Anderson (b) (4)	14 Aug 2020 14:51:42

US3412067

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	14 Aug 2020 14:51:42

US3412067

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	Steven Anderson (b) (4)	14 Aug 2020 14:51:42

US3412067

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	14 Aug 2020 14:51:47

US3412067

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User entered 'I'	System	14 Aug 2020 14:51:47

US3412067

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:55:53

US3412067

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '21 Aug 2020'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:55:53

US3412067

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:55:53

US3412067

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:55:53

US3412067

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	24 Aug 2020 21:56:00

US3412067

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User entered 'I'	System	24 Aug 2020 21:56:00

US3412067

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Aug 2020 13:55:22

US3412067

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '28 Aug 2020'	Steven Anderson (b) (4)	28 Aug 2020 13:55:22

US3412067

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	28 Aug 2020 13:55:22

US3412067

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'VISIT2'	System	28 Aug 2020 13:55:22

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	28 Aug 2020 13:56:18
	(b) (4)	

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '28 Aug 2020'	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '09:03'	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered '28 Aug 2020 09:03'	System	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '36.6' C	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '82'	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'bpm'	System	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '17'	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'breaths/min'	System	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '126'	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'mmHg'	System	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '78'	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'mmHg'	System	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	17 Sep 2020 13:06:49
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Sep 2020 13:06:49
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Sep 2020 13:06:49
User opened query 'Data is required. Please complete.' (Site from System).	System	28 Aug 2020 13:56:18
User entered empty.	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '28 Aug 2020' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 13:06:49
User entered empty.	Mylene Asmar-Rios (b) (4)	28 Aug 2020 13:56:18
	(b) (4)	

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '10:17' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 13:06:49
User entered empty.	Mylene Asmar-Rios (b) (4)	28 Aug 2020 13:56:18
	(b) (4)	

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered '28 Aug 2020 10:17'	System	17 Sep 2020 13:06:49
User entered empty.	System	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
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) (4), (b) (6)	21 Sep 2020 08:22:30
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.'	Mylene Asmar-Rios (b) (4)	17 Sep 2020 14:11:32
answered with 'As per protocol the temp is considered within normal range ' (Site from System).		
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	17 Sep 2020 13:06:49
User entered '96.5' F reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	17 Sep 2020 13:06:49
User entered empty.	Steven Anderson (b) (4) (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 13:06:49
User entered empty.	Mylene Asmar-Rios (b) (4)	28 Aug 2020 13:56:18
	(b) (4)	

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Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '62' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 13:06:49
User entered empty.	Mylene Asmar-Rios (b) (4)	28 Aug 2020 13:56:18
	(b) (4)	

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'bpm'	System	17 Sep 2020 13:06:49
User entered empty.	System	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '18' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 13:06:49
User entered empty.	Mylene Asmar-Rios (b) (4)	28 Aug 2020 13:56:18
	(b) (4)	

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'breaths/min'	System	17 Sep 2020 13:06:49
User entered empty.	System	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '124' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 13:06:49
User entered empty.	Mylene Asmar-Rios (b) (4)	28 Aug 2020 13:56:18
	(b) (4)	

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'mmHg'	System	17 Sep 2020 13:06:49
User entered empty.	System	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '72' reason for change: Data Entry Error	(b) (4)	17 Sep 2020 13:06:49
User entered empty.	Mylene Asmar-Rios (b) (4)	28 Aug 2020 13:56:18
	(b) (4)	

US3412067

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'mmHg'	System	17 Sep 2020 13:06:49
User entered empty.	System	28 Aug 2020 13:56:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Aug 2020 13:56:29

US3412067

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '28 Aug 2020'	Steven Anderson (b) (4)	28 Aug 2020 13:56:29

US3412067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Aug 2020 13:57:38

US3412067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	28 Aug 2020 13:57:38

US3412067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	28 Aug 2020 13:57:38

US3412067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'MRNA-1273 OR PLACEBO'	System	28 Aug 2020 13:57:38

US3412067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '28 Aug 2020'	Steven Anderson (b) (4)	28 Aug 2020 13:57:38

US3412067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '09:45'	Steven Anderson (b) (4)	28 Aug 2020 13:57:38

US3412067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered '28 Aug 2020 09:45'	System	28 Aug 2020 13:57:38

US3412067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	28 Aug 2020 13:57:38

US3412067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'ONCE'	System	28 Aug 2020 13:57:38

US3412067

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:29:16

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'INTRAMUSCULAR'	System	28 Aug 2020 13:57:38

US3412067

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Aug 2020 13:57:58

US3412067

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '28 Aug 2020'	Steven Anderson (b) (4)	28 Aug 2020 13:57:58

US3412067

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '09:28'	Steven Anderson (b) (4)	28 Aug 2020 13:57:58

US3412067

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered '28 Aug 2020 09:28'	System	28 Aug 2020 13:57:58

US3412067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:29:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '28 Aug 2020'	Steven Anderson (b) (4)	28 Aug 2020 13:58:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	28 Aug 2020 13:58:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Aug 2020 13:58:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '09:34'	Steven Anderson (b) (4)	28 Aug 2020 13:58:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered '28 Aug 2020 09:34'	System	28 Aug 2020 13:58:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:16

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	28 Aug 2020 13:58:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'No (N)'	Steven Anderson (b) (4)	28 Aug 2020 13:58:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	28 Aug 2020 13:58:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered empty.	System	28 Aug 2020 13:58:18

US3412067

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	28 Aug 2020 13:58:23

US3412067

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'I'	System	28 Aug 2020 13:58:23

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:23:29', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '46c10445-604e-4b23-8c6d-d36600922b77'	System	28 Aug 2020 14:23:57
User entered 'Yes (Y)'	System	28 Aug 2020 14:23:57

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:23:35', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '46c10445-604e-4b23-8c6d-d36600922b77'	System	28 Aug 2020 14:23:57
User entered '96.5'	System	28 Aug 2020 14:23:57

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:23:42', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '46c10445-604e-4b23-8c6d-d36600922b77'	System	28 Aug 2020 14:23:57
User entered 'No (N)'	System	28 Aug 2020 14:23:57

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:23:55', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '46c10445-604e-4b23-8c6d-d36600922b77'	System	28 Aug 2020 14:23:57
User entered '28 Aug 2020 10:23'	System	28 Aug 2020 14:23:57

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '28 Aug 2020 10:05'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '28 Aug 2020 12:35'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:04:32', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd82359b1-9f0f-447b-a2a1-f2a203dba9b7'	System	28 Aug 2020 22:05:22
User entered 'Yes (Y)'	System	28 Aug 2020 22:05:22

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:04:41', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd82359b1-9f0f-447b-a2a1-f2a203dba9b7'	System	28 Aug 2020 22:05:22
User entered '97.7'	System	28 Aug 2020 22:05:22

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:04:46', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd82359b1-9f0f-447b-a2a1-f2a203dba9b7'	System	28 Aug 2020 22:05:22
User entered 'No (N)'	System	28 Aug 2020 22:05:22

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:05:19', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd82359b1-9f0f-447b-a2a1-f2a203dba9b7'	System	28 Aug 2020 22:05:22
User entered '28 Aug 2020 18:05'	System	28 Aug 2020 22:05:22

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '28 Aug 2020 13:30'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 2'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:43:49', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9ea245c4-5945-4856-ae5c-d1b251d30965'	System	29 Aug 2020 22:44:08
User entered 'Yes (Y)'	System	29 Aug 2020 22:44:08

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:43:56', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9ea245c4-5945-4856-ae5c-d1b251d30965'	System	29 Aug 2020 22:44:08
User entered '97.2'	System	29 Aug 2020 22:44:08

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:43:59', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9ea245c4-5945-4856-ae5c-d1b251d30965'	System	29 Aug 2020 22:44:08
User entered 'No (N)'	System	29 Aug 2020 22:44:08

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:44:04', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9ea245c4-5945-4856-ae5c-d1b251d30965'	System	29 Aug 2020 22:44:08
User entered '29 Aug 2020 18:44'	System	29 Aug 2020 22:44:08

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 3'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:33:42', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '5ea384a7-803f-477d-84ec-414fd4484a7e'	System	31 Aug 2020 00:38:31
User entered 'Yes (Y)'	System	31 Aug 2020 00:38:31

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:33:52', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '5ea384a7-803f-477d-84ec-414fd4484a7e'	System	31 Aug 2020 00:38:31
User entered '97.8'	System	31 Aug 2020 00:38:31

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:34:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '5ea384a7-803f-477d-84ec-414fd4484a7e'	System	31 Aug 2020 00:38:31
User entered 'No (N)'	System	31 Aug 2020 00:38:31

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:34:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '5ea384a7-803f-477d-84ec-414fd4484a7e'	System	31 Aug 2020 00:38:31
User entered '30 Aug 2020 20:34'	System	31 Aug 2020 00:38:31

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 4'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:38:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2568a263-0eb6-437e-8a68-9d4c6533254b'	System	31 Aug 2020 21:38:41
User entered 'Yes (Y)'	System	31 Aug 2020 21:38:41

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:38:19', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2568a263-0eb6-437e-8a68-9d4c6533254b'	System	31 Aug 2020 21:38:41
User entered '97.7'	System	31 Aug 2020 21:38:41

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:38:24', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2568a263-0eb6-437e-8a68-9d4c6533254b'	System	31 Aug 2020 21:38:41
User entered 'No (N)'	System	31 Aug 2020 21:38:41

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:38:36', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2568a263-0eb6-437e-8a68-9d4c6533254b'	System	31 Aug 2020 21:38:41
User entered '31 Aug 2020 17:38'	System	31 Aug 2020 21:38:41

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 5'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:47:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '0c7dde31-b2fd-43e8-96ba-1850fe05b7a3'	System	02 Sep 2020 00:47:31
User entered 'Yes (Y)'	System	02 Sep 2020 00:47:31

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:47:16', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '0c7dde31-b2fd-43e8-96ba-1850fe05b7a3'	System	02 Sep 2020 00:47:31
User entered '97.9'	System	02 Sep 2020 00:47:31

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:47:20', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '0c7dde31-b2fd-43e8-96ba-1850fe05b7a3'	System	02 Sep 2020 00:47:31
User entered 'No (N)'	System	02 Sep 2020 00:47:31

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:47:29', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '0c7dde31-b2fd-43e8-96ba-1850fe05b7a3'	System	02 Sep 2020 00:47:31
User entered '01 Sep 2020 20:47'	System	02 Sep 2020 00:47:31

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 6'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:54:33', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '402922d1-6af4-4a55-a8db-1bc171ea6cb5'	System	03 Sep 2020 00:55:03
User entered 'Yes (Y)'	System	03 Sep 2020 00:55:03

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:54:40', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '402922d1-6af4-4a55-a8db-1bc171ea6cb5'	System	03 Sep 2020 00:55:03
User entered '97.6'	System	03 Sep 2020 00:55:03

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:54:46', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '402922d1-6af4-4a55-a8db-1bc171ea6cb5'	System	03 Sep 2020 00:55:03
User entered 'No (N)'	System	03 Sep 2020 00:55:03

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:54:58', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '402922d1-6af4-4a55-a8db-1bc171ea6cb5'	System	03 Sep 2020 00:55:03
User entered '02 Sep 2020 20:54'	System	03 Sep 2020 00:55:03

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 7'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:24:09', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1a773ab2-5bc4-479f-80df-3c321434f613'	System	28 Aug 2020 14:25:22
User entered 'None (1)'	System	28 Aug 2020 14:25:22

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:24:21', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1a773ab2-5bc4-479f-80df-3c321434f613'	System	28 Aug 2020 14:25:22
User entered 'No (N)'	System	28 Aug 2020 14:25:22

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:24:28', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1a773ab2-5bc4-479f-80df-3c321434f613'	System	28 Aug 2020 14:25:22
User entered 'No (N)'	System	28 Aug 2020 14:25:22

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:25:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1a773ab2-5bc4-479f-80df-3c321434f613'	System	28 Aug 2020 14:25:22
User entered 'None (1)'	System	28 Aug 2020 14:25:22

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:25:20', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1a773ab2-5bc4-479f-80df-3c321434f613'	System	28 Aug 2020 14:25:22
User entered '28 Aug 2020 10:25'	System	28 Aug 2020 14:25:22

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '28 Aug 2020 10:05'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '28 Aug 2020 12:35'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:05', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '0eb2361b-bb5d-4f9e-9660-9326797c1652'	System	28 Aug 2020 22:07:33
User entered 'None (1)'	System	28 Aug 2020 22:07:33

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '0eb2361b-bb5d-4f9e-9660-9326797c1652'	System	28 Aug 2020 22:07:33
User entered 'No (N)'	System	28 Aug 2020 22:07:33

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:13', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '0eb2361b-bb5d-4f9e-9660-9326797c1652'	System	28 Aug 2020 22:07:33
User entered 'No (N)'	System	28 Aug 2020 22:07:33

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:19', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '0eb2361b-bb5d-4f9e-9660-9326797c1652'	System	28 Aug 2020 22:07:33
User entered 'None (1)'	System	28 Aug 2020 22:07:33

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:30', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '0eb2361b-bb5d-4f9e-9660-9326797c1652'	System	28 Aug 2020 22:07:33
User entered '28 Aug 2020 18:07'	System	28 Aug 2020 22:07:33

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '28 Aug 2020 13:30'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 2'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:44:16', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'c09467a2-5019-46b3-afce-c5481f5bea30'	System	29 Aug 2020 22:44:57
User entered 'None (1)'	System	29 Aug 2020 22:44:57

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:44:21', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'c09467a2-5019-46b3-afce-c5481f5bea30'	System	29 Aug 2020 22:44:57
User entered 'No (N)'	System	29 Aug 2020 22:44:57

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:44:39', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'c09467a2-5019-46b3-afce-c5481f5bea30'	System	29 Aug 2020 22:44:57
User entered 'No (N)'	System	29 Aug 2020 22:44:57

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:44:46', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'c09467a2-5019-46b3-afce-c5481f5bea30'	System	29 Aug 2020 22:44:57
User entered 'None (1)'	System	29 Aug 2020 22:44:57

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:44:53', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'c09467a2-5019-46b3-afce-c5481f5bea30'	System	29 Aug 2020 22:44:57
User entered '29 Aug 2020 18:44'	System	29 Aug 2020 22:44:57

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 3'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:34:22', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a27bc2e0-4d09-4d60-8d38-d03b5204b1e3'	System	31 Aug 2020 00:38:45
User entered 'None (1)'	System	31 Aug 2020 00:38:45

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:34:25', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a27bc2e0-4d09-4d60-8d38-d03b5204b1e3'	System	31 Aug 2020 00:38:45
User entered 'No (N)'	System	31 Aug 2020 00:38:45

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:34:30', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a27bc2e0-4d09-4d60-8d38-d03b5204b1e3'	System	31 Aug 2020 00:38:45
User entered 'No (N)'	System	31 Aug 2020 00:38:45

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:34:49', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a27bc2e0-4d09-4d60-8d38-d03b5204b1e3'	System	31 Aug 2020 00:38:45
User entered 'None (1)'	System	31 Aug 2020 00:38:45

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:34:58', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a27bc2e0-4d09-4d60-8d38-d03b5204b1e3'	System	31 Aug 2020 00:38:45
User entered '30 Aug 2020 20:34'	System	31 Aug 2020 00:38:45

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 4'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:38:49', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'c1db187b-9e4d-41ed-9600-78917ff305fe'	System	31 Aug 2020 21:39:43
User entered 'None (1)'	System	31 Aug 2020 21:39:43

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:39:04', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'c1db187b-9e4d-41ed-9600-78917ff305fe'	System	31 Aug 2020 21:39:43
User entered 'No (N)'	System	31 Aug 2020 21:39:43

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:39:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'c1db187b-9e4d-41ed-9600-78917ff305fe'	System	31 Aug 2020 21:39:43
User entered 'No (N)'	System	31 Aug 2020 21:39:43

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:39:34', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'c1db187b-9e4d-41ed-9600-78917ff305fe'	System	31 Aug 2020 21:39:43
User entered 'None (1)'	System	31 Aug 2020 21:39:43

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:39:40', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'c1db187b-9e4d-41ed-9600-78917ff305fe'	System	31 Aug 2020 21:39:43
User entered '31 Aug 2020 17:39'	System	31 Aug 2020 21:39:43

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 5'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:47:36', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '45909b3e-c5f0-41ff-a2a6-b88b99553897'	System	02 Sep 2020 00:48:19
User entered 'None (1)'	System	02 Sep 2020 00:48:19

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:47:42', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '45909b3e-c5f0-41ff-a2a6-b88b99553897'	System	02 Sep 2020 00:48:19
User entered 'No (N)'	System	02 Sep 2020 00:48:19

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:47:48', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '45909b3e-c5f0-41ff-a2a6-b88b99553897'	System	02 Sep 2020 00:48:19
User entered 'No (N)'	System	02 Sep 2020 00:48:19

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:48:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '45909b3e-c5f0-41ff-a2a6-b88b99553897'	System	02 Sep 2020 00:48:19
User entered 'None (1)'	System	02 Sep 2020 00:48:19

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:48:16', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '45909b3e-c5f0-41ff-a2a6-b88b99553897'	System	02 Sep 2020 00:48:19
User entered '01 Sep 2020 20:48'	System	02 Sep 2020 00:48:19

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 6'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:55:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '09073547-28d9-438b-9d68-8f4318a4fea2'	System	03 Sep 2020 00:55:59
User entered 'None (1)'	System	03 Sep 2020 00:55:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:55:16', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '09073547-28d9-438b-9d68-8f4318a4fea2'	System	03 Sep 2020 00:55:59
User entered 'No (N)'	System	03 Sep 2020 00:55:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:55:21', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '09073547-28d9-438b-9d68-8f4318a4fea2'	System	03 Sep 2020 00:55:59
User entered 'No (N)'	System	03 Sep 2020 00:55:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:55:47', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '09073547-28d9-438b-9d68-8f4318a4fea2'	System	03 Sep 2020 00:55:59
User entered 'None (1)'	System	03 Sep 2020 00:55:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:55:56', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '09073547-28d9-438b-9d68-8f4318a4fea2'	System	03 Sep 2020 00:55:59
User entered '02 Sep 2020 20:55'	System	03 Sep 2020 00:55:59

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 7'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:25:34', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'aa62c34f-3218-4653-9ab4-713ea11ce9b1'	System	28 Aug 2020 14:26:27
User entered 'None (0)'	System	28 Aug 2020 14:26:27

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:25:41', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'aa62c34f-3218-4653-9ab4-713ea11ce9b1'	System	28 Aug 2020 14:26:27
User entered 'None (0)'	System	28 Aug 2020 14:26:27

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:25:47', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'aa62c34f-3218-4653-9ab4-713ea11ce9b1'	System	28 Aug 2020 14:26:27
User entered 'None (0)'	System	28 Aug 2020 14:26:27

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:25:51', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'aa62c34f-3218-4653-9ab4-713ea11ce9b1'	System	28 Aug 2020 14:26:27
User entered 'None (0)'	System	28 Aug 2020 14:26:27

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:25:57', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'aa62c34f-3218-4653-9ab4-713ea11ce9b1'	System	28 Aug 2020 14:26:27
User entered 'None (0)'	System	28 Aug 2020 14:26:27

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:26:01', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'aa62c34f-3218-4653-9ab4-713ea11ce9b1'	System	28 Aug 2020 14:26:27
User entered 'None (0)'	System	28 Aug 2020 14:26:27

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:26:06', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'aa62c34f-3218-4653-9ab4-713ea11ce9b1'	System	28 Aug 2020 14:26:27
User entered 'No (N)'	System	28 Aug 2020 14:26:27

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T10:26:25', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'aa62c34f-3218-4653-9ab4-713ea11ce9b1'	System	28 Aug 2020 14:26:27
User entered '28 Aug 2020 10:26'	System	28 Aug 2020 14:26:27

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '28 Aug 2020 10:05'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '28 Aug 2020 12:35'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 1, after vaccination (at home)'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:35', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '403822ad-f58c-4967-92a6-5f4f085b5782'	System	28 Aug 2020 22:08:06
User entered 'None (0)'	System	28 Aug 2020 22:08:06

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:38', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '403822ad-f58c-4967-92a6-5f4f085b5782'	System	28 Aug 2020 22:08:06
User entered 'None (0)'	System	28 Aug 2020 22:08:06

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:42', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '403822ad-f58c-4967-92a6-5f4f085b5782'	System	28 Aug 2020 22:08:06
User entered 'None (0)'	System	28 Aug 2020 22:08:06

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:47', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '403822ad-f58c-4967-92a6-5f4f085b5782'	System	28 Aug 2020 22:08:06
User entered 'None (0)'	System	28 Aug 2020 22:08:06

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:50', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '403822ad-f58c-4967-92a6-5f4f085b5782'	System	28 Aug 2020 22:08:06
User entered 'None (0)'	System	28 Aug 2020 22:08:06

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:53', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '403822ad-f58c-4967-92a6-5f4f085b5782'	System	28 Aug 2020 22:08:06
User entered 'None (0)'	System	28 Aug 2020 22:08:06

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:07:57', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '403822ad-f58c-4967-92a6-5f4f085b5782'	System	28 Aug 2020 22:08:06
User entered 'No (N)'	System	28 Aug 2020 22:08:06

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-28T18:08:03', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '403822ad-f58c-4967-92a6-5f4f085b5782'	System	28 Aug 2020 22:08:06
User entered '28 Aug 2020 18:08'	System	28 Aug 2020 22:08:06

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '28 Aug 2020 13:30'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '29 Aug 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 2'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:44:58', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83916ac9-07ac-47e2-a2d1-e0b090d74781'	System	29 Aug 2020 22:45:30
User entered 'None (0)'	System	29 Aug 2020 22:45:30

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:45:01', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83916ac9-07ac-47e2-a2d1-e0b090d74781'	System	29 Aug 2020 22:45:30
User entered 'None (0)'	System	29 Aug 2020 22:45:30

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:45:03', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83916ac9-07ac-47e2-a2d1-e0b090d74781'	System	29 Aug 2020 22:45:30
User entered 'None (0)'	System	29 Aug 2020 22:45:30

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:45:06', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83916ac9-07ac-47e2-a2d1-e0b090d74781'	System	29 Aug 2020 22:45:30
User entered 'None (0)'	System	29 Aug 2020 22:45:30

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:45:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83916ac9-07ac-47e2-a2d1-e0b090d74781'	System	29 Aug 2020 22:45:30
User entered 'None (0)'	System	29 Aug 2020 22:45:30

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:45:13', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83916ac9-07ac-47e2-a2d1-e0b090d74781'	System	29 Aug 2020 22:45:30
User entered 'None (0)'	System	29 Aug 2020 22:45:30

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:45:17', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83916ac9-07ac-47e2-a2d1-e0b090d74781'	System	29 Aug 2020 22:45:30
User entered 'No (N)'	System	29 Aug 2020 22:45:30

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-29T18:45:24', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '83916ac9-07ac-47e2-a2d1-e0b090d74781'	System	29 Aug 2020 22:45:30
User entered '29 Aug 2020 18:45'	System	29 Aug 2020 22:45:30

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '29 Aug 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '30 Aug 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 3'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:35:04', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'daf39b19-b957-46ce-ab1a-c4f6f6ecacbd'	System	31 Aug 2020 00:39:07
User entered 'None (0)'	System	31 Aug 2020 00:39:07

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:35:08', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'daf39b19-b957-46ce-ab1a-c4f6f6ecacbd'	System	31 Aug 2020 00:39:07
User entered 'None (0)'	System	31 Aug 2020 00:39:07

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:35:13', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'daf39b19-b957-46ce-ab1a-c4f6f6ecacbd'	System	31 Aug 2020 00:39:07
User entered 'None (0)'	System	31 Aug 2020 00:39:07

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:35:38', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'daf39b19-b957-46ce-ab1a-c4f6f6ecacbd'	System	31 Aug 2020 00:39:07
User entered 'None (0)'	System	31 Aug 2020 00:39:07

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:35:43', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'daf39b19-b957-46ce-ab1a-c4f6f6ecacbd'	System	31 Aug 2020 00:39:07
User entered 'None (0)'	System	31 Aug 2020 00:39:07

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:35:46', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'daf39b19-b957-46ce-ab1a-c4f6f6ecacbd'	System	31 Aug 2020 00:39:07
User entered 'None (0)'	System	31 Aug 2020 00:39:07

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:35:53', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'daf39b19-b957-46ce-ab1a-c4f6f6ecacbd'	System	31 Aug 2020 00:39:07
User entered 'No (N)'	System	31 Aug 2020 00:39:07

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-30T20:36:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'daf39b19-b957-46ce-ab1a-c4f6f6ecacbd'	System	31 Aug 2020 00:39:07
User entered '30 Aug 2020 20:36'	System	31 Aug 2020 00:39:07

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '30 Aug 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Aug 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 4'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:39:55', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '23c79c24-475d-4520-a3ce-d9a22e6656d7'	System	31 Aug 2020 21:40:47
User entered 'None (0)'	System	31 Aug 2020 21:40:47

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:39:58', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '23c79c24-475d-4520-a3ce-d9a22e6656d7'	System	31 Aug 2020 21:40:47
User entered 'None (0)'	System	31 Aug 2020 21:40:47

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:40:02', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '23c79c24-475d-4520-a3ce-d9a22e6656d7'	System	31 Aug 2020 21:40:47
User entered 'None (0)'	System	31 Aug 2020 21:40:47

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:40:09', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '23c79c24-475d-4520-a3ce-d9a22e6656d7'	System	31 Aug 2020 21:40:47
User entered 'None (0)'	System	31 Aug 2020 21:40:47

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:40:12', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '23c79c24-475d-4520-a3ce-d9a22e6656d7'	System	31 Aug 2020 21:40:47
User entered 'None (0)'	System	31 Aug 2020 21:40:47

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:40:18', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '23c79c24-475d-4520-a3ce-d9a22e6656d7'	System	31 Aug 2020 21:40:47
User entered 'None (0)'	System	31 Aug 2020 21:40:47

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:40:38', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '23c79c24-475d-4520-a3ce-d9a22e6656d7'	System	31 Aug 2020 21:40:47
User entered 'No (N)'	System	31 Aug 2020 21:40:47

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-08-31T17:40:44', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '23c79c24-475d-4520-a3ce-d9a22e6656d7'	System	31 Aug 2020 21:40:47
User entered '31 Aug 2020 17:40'	System	31 Aug 2020 21:40:47

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '31 Aug 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 5'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:48:21', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f3546abe-bfea-4bbb-a4bd-bfddc4584e74'	System	02 Sep 2020 00:49:31
User entered 'None (0)'	System	02 Sep 2020 00:49:31

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:48:30', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f3546abe-bfea-4bbb-a4bd-bfddc4584e74'	System	02 Sep 2020 00:49:31
User entered 'None (0)'	System	02 Sep 2020 00:49:31

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:48:35', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f3546abe-bfea-4bbb-a4bd-bfddc4584e74'	System	02 Sep 2020 00:49:31
User entered 'None (0)'	System	02 Sep 2020 00:49:31

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:48:42', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f3546abe-bfea-4bbb-a4bd-bfddc4584e74'	System	02 Sep 2020 00:49:31
User entered 'None (0)'	System	02 Sep 2020 00:49:31

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:48:44', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f3546abe-bfea-4bbb-a4bd-bfddc4584e74'	System	02 Sep 2020 00:49:31
User entered 'None (0)'	System	02 Sep 2020 00:49:31

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:48:48', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f3546abe-bfea-4bbb-a4bd-bfddc4584e74'	System	02 Sep 2020 00:49:31
User entered 'None (0)'	System	02 Sep 2020 00:49:31

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:48:53', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f3546abe-bfea-4bbb-a4bd-bfddc4584e74'	System	02 Sep 2020 00:49:31
User entered 'No (N)'	System	02 Sep 2020 00:49:31

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-01T20:49:24', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'f3546abe-bfea-4bbb-a4bd-bfddc4584e74'	System	02 Sep 2020 00:49:31
User entered '01 Sep 2020 20:49'	System	02 Sep 2020 00:49:31

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '01 Sep 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 6'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:56:34', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'cf6c9a0e-02a3-443c-856f-94045cb9d488'	System	03 Sep 2020 00:57:14
User entered 'No interference with activity (1)'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:56:38', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'cf6c9a0e-02a3-443c-856f-94045cb9d488'	System	03 Sep 2020 00:57:14
User entered 'None (0)'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:56:43', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'cf6c9a0e-02a3-443c-856f-94045cb9d488'	System	03 Sep 2020 00:57:14
User entered 'None (0)'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:56:47', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'cf6c9a0e-02a3-443c-856f-94045cb9d488'	System	03 Sep 2020 00:57:14
User entered 'None (0)'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:56:51', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'cf6c9a0e-02a3-443c-856f-94045cb9d488'	System	03 Sep 2020 00:57:14
User entered 'None (0)'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:56:54', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'cf6c9a0e-02a3-443c-856f-94045cb9d488'	System	03 Sep 2020 00:57:14
User entered 'None (0)'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:57:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'cf6c9a0e-02a3-443c-856f-94045cb9d488'	System	03 Sep 2020 00:57:14
User entered 'No (N)'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-02T20:57:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'cf6c9a0e-02a3-443c-856f-94045cb9d488'	System	03 Sep 2020 00:57:14
User entered '02 Sep 2020 20:57'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '02 Sep 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	28 Aug 2020 13:57:38
User entered 'Day 7'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '03 Sep 2020 12:00'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '04 Sep 2020 11:59'	System	28 Aug 2020 13:57:38

US3412067

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	03 Sep 2020 00:57:14
User entered 'Day 8'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-04T15:56:54', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd643aba6-06e6-4988-8eb7-faa64d568475'	System	04 Sep 2020 19:57:02
User entered 'None (0)'	System	04 Sep 2020 19:57:02

US3412067

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:29:16

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-04T15:57:01', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd643aba6-06e6-4988-8eb7-faa64d568475'	System	04 Sep 2020 19:57:02
User entered '04 Sep 2020 15:57'	System	04 Sep 2020 19:57:02

US3412067

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	03 Sep 2020 00:57:14
User entered 'Day 8'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-04T15:57:06', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7eea944e-47b2-4eac-8993-ca0b87af8c7f'	System	04 Sep 2020 19:57:11
User entered 'No (N)'	System	04 Sep 2020 19:57:11

US3412067

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:29:16

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-09-04T15:57:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7eea944e-47b2-4eac-8993-ca0b87af8c7f'	System	04 Sep 2020 19:57:11
User entered '04 Sep 2020 15:57'	System	04 Sep 2020 19:57:11

US3412067

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:29:16

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '04 Sep 2020 12:00'	System	03 Sep 2020 00:57:14

US3412067

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:29:16

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
User entered '05 Sep 2020 11:59'	System	03 Sep 2020 00:57:14

US3412067

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:49:06

US3412067

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered '04 Sep 2020'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:49:06

US3412067

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:49:06

US3412067

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:49:06

US3412067

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:25:18
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Sep 2020 12:49:11

US3412067

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User entered 'I'	System	04 Sep 2020 12:49:11

US3412067

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Sep 2020 16:34:47

US3412067

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '11 Sep 2020'	Mason Urban (b) (4)	11 Sep 2020 16:34:47

US3412067

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	11 Sep 2020 16:34:47

US3412067

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Mason Urban (b) (4)	11 Sep 2020 16:34:47

US3412067

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Sep 2020 16:34:54

US3412067

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User entered 'I'	System	11 Sep 2020 16:34:54

US3412067

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	18 Sep 2020 13:35:47

US3412067

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '18 Sep 2020'	Mason Urban (b) (4)	18 Sep 2020 13:35:47

US3412067

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	18 Sep 2020 13:35:47

US3412067

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Mason Urban (b) (4)	18 Sep 2020 13:35:47

US3412067

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Mason Urban (b) (4)	18 Sep 2020 13:35:51

US3412067

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User entered 'I'	System	18 Sep 2020 13:35:51

US3412067

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	25 Sep 2020 12:43:58

US3412067

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '25 Sep 2020'	Steven Anderson (b) (4)	25 Sep 2020 12:43:58

US3412067

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	25 Sep 2020 12:43:58

US3412067

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'VISIT3'	System	25 Sep 2020 12:43:58

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'No (N)'	Steven Anderson (b) (4)	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered empty.	System	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered empty.	System	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered empty.	System	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered empty.	System	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty.	Steven Anderson (b) (4)	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered empty.	System	25 Sep 2020 12:44:08

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42

US3412067

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42

US3412067

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	29 Dec 2020 18:35:50
User entered 'Yes (Y)'	Steven Anderson (b) (4)	25 Sep 2020 12:44:22

US3412067

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	29 Dec 2020 18:35:50
User entered '25 Sep 2020'	Steven Anderson (b) (4)	25 Sep 2020 12:44:22

US3412067

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	25 Sep 2020 12:44:44

US3412067

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '25 Sep 2020'	Steven Anderson (b) (4)	25 Sep 2020 12:44:44

US3412067

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered '08:28'	Steven Anderson (b) (4)	25 Sep 2020 12:44:44

US3412067

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered '25 Sep 2020 08:28'	System	25 Sep 2020 12:44:44

US3412067

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:48:44
User entered 'Yes (Y)'	Steven Anderson (b) (4)	25 Sep 2020 12:44:49

US3412067

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:42
User entered 'I'	System	25 Sep 2020 12:44:49

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 64'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '30 Sep 2020 00:01'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '04 Oct 2020 23:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 71'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-10-08T08:03:13', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '528e6110-fdd6-4899-8e9c-e095aaf3988d'	System	08 Oct 2020 12:03:25
User entered 'No (N)'	System	08 Oct 2020 12:03:25

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Have you been exposed to someone with 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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-10-08T08:03:17', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '528e6110-fdd6-4899-8e9c-e095aaf3988d'	System	08 Oct 2020 12:03:25
User entered 'No (N)'	System	08 Oct 2020 12:03:25

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-10-08T08:03:22', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '528e6110-fdd6-4899-8e9c-e095aaf3988d'	System	08 Oct 2020 12:03:25
User entered '08 Oct 2020 08:03:22'	System	08 Oct 2020 12:03:25

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '07 Oct 2020 00:01'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '11 Oct 2020 23:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 78'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-10-18T09:15:08', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ee2fb3d9-18db-43ed-8959-9ba3edcaece4'	System	18 Oct 2020 13:15:34
User entered 'No (N)'	System	18 Oct 2020 13:15:34

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Have you been exposed to someone with 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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-10-18T09:15:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ee2fb3d9-18db-43ed-8959-9ba3edcaece4'	System	18 Oct 2020 13:15:34
User entered 'No (N)'	System	18 Oct 2020 13:15:34

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-10-18T09:15:28', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ee2fb3d9-18db-43ed-8959-9ba3edcaece4'	System	18 Oct 2020 13:15:34
User entered '18 Oct 2020 09:15:28'	System	18 Oct 2020 13:15:34

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '14 Oct 2020 00:01'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '18 Oct 2020 23:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 92'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-10-31T05:18:07', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '15495bdf-a58a-4c67-8817-0de18323988f'	System	31 Oct 2020 09:18:18
User entered 'No (N)'	System	31 Oct 2020 09:18:18

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-10-31T05:18:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '15495bdf-a58a-4c67-8817-0de18323988f'	System	31 Oct 2020 09:18:18
User entered 'No (N)'	System	31 Oct 2020 09:18:18

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-10-31T05:18:15', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '15495bdf-a58a-4c67-8817-0de18323988f'	System	31 Oct 2020 09:18:18
User entered '31 Oct 2020 05:18:15'	System	31 Oct 2020 09:18:18

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '28 Oct 2020 00:01'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '01 Nov 2020 23:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 99'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-11-04T05:23:45', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '091a41ad-7c82-408c-8149-e37995539525'	System	04 Nov 2020 10:24:01
User entered 'No (N)'	System	04 Nov 2020 10:24:01

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-11-04T05:23:52', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '091a41ad-7c82-408c-8149-e37995539525'	System	04 Nov 2020 10:24:01
User entered 'No (N)'	System	04 Nov 2020 10:24:01

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (6fc1fbc7ea0b1dd7)', Time: '2020-11-04T05:23:59', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '091a41ad-7c82-408c-8149-e37995539525'	System	04 Nov 2020 10:24:01
User entered '04 Nov 2020 05:23:59'	System	04 Nov 2020 10:24:01

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '04 Nov 2020 00:01'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:49:41
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '08 Nov 2020 23:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 106'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '11 Nov 2020 00:01'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '15 Nov 2020 23:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46
Data entry locked.	System	31 Jul 2020 16:22:15
User entered 'Day 113'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

US3412067

Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46

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Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '18 Nov 2020 00:01'	System	31 Jul 2020 16:22:15

US3412067

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 10:54:46
Data entry locked.	System	31 Jul 2020 16:22:15
User entered '22 Nov 2020 23:59'	System	31 Jul 2020 16:22:15

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

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)
User closed query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 12:18:39
Query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' answered with 'subject was exposed to his mom who had tested positive for covid19. subject was supposed to see their pcip for their OA but cancelled due to their covid exposure' (Site from DM).	Andrea Newlands (b) (4)	09 Apr 2021 15:06:12
User opened query 'Per DM CLR: Any changes since last questionnaire or contact with study clinic?; and Have you contacted a healthcare provider since last questionnaire or study contact? = YES, however, there is no corresponding AE recorded for this information in the AE eCRF page. Please confirm and update if a Medically-attended AE should be recorded, otherwise provide clarification.' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 03:15:19
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2020-11-25T12:58:47', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ec9f1a6b-e7fb-4c8a-b601-d5d7e36ee085'	System	25 Nov 2020 17:59:49
User entered 'Yes (Y)'	System	25 Nov 2020 17:59:49

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2020-11-25T12:58:55', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ec9f1a6b-e7fb-4c8a-b601-d5d7e36ee085'	System	25 Nov 2020 17:59:49
User entered 'Yes (Y)'	System	25 Nov 2020 17:59:49

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Please 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 (8b1ba14bae57953d)', Time: '2020-11-25T12:59:04', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ec9f1a6b-e7fb-4c8a-b601-d5d7e36ee085'	System	25 Nov 2020 17:59:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 17:59:49

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2020-11-25T12:59:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ec9f1a6b-e7fb-4c8a-b601-d5d7e36ee085'	System	25 Nov 2020 17:59:49
User entered 'No (N)'	System	25 Nov 2020 17:59:49

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2020-11-25T12:59:19', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ec9f1a6b-e7fb-4c8a-b601-d5d7e36ee085'	System	25 Nov 2020 17:59:49
User entered 'Yes (Y)'	System	25 Nov 2020 17:59:49

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Please 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 (8b1ba14bae57953d)', Time: '2020-11-25T12:59:25', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ec9f1a6b-e7fb-4c8a-b601-d5d7e36ee085'	System	25 Nov 2020 17:59:49
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	25 Nov 2020 17:59:49

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2020-11-25T12:59:40', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'ec9f1a6b-e7fb-4c8a-b601-d5d7e36ee085'	System	25 Nov 2020 17:59:49
User entered '25 Nov 2020 12:59:40'	System	25 Nov 2020 17:59:49

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '22 Nov 2020 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '26 Nov 2020 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2020-11-29T07:28:58', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'dbe69ef2-d93c-4897-a903-2c4f0181352b'	System	29 Nov 2020 12:29:20
User entered 'No (N)'	System	29 Nov 2020 12:29:20

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2020-11-29T07:29:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'dbe69ef2-d93c-4897-a903-2c4f0181352b'	System	29 Nov 2020 12:29:20
User entered 'No (N)'	System	29 Nov 2020 12:29:20

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2020-11-29T07:29:19', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'dbe69ef2-d93c-4897-a903-2c4f0181352b'	System	29 Nov 2020 12:29:20
User entered '29 Nov 2020 07:29:19'	System	29 Nov 2020 12:29:20

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '29 Nov 2020 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '03 Dec 2020 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2020-12-06T07:44:53', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '873512b2-b2b8-4af1-ba14-b890661a781e'	System	06 Dec 2020 12:45:12
User entered 'No (N)'	System	06 Dec 2020 12:45:12

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2020-12-06T07:44:59', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '873512b2-b2b8-4af1-ba14-b890661a781e'	System	06 Dec 2020 12:45:12
User entered 'No (N)'	System	06 Dec 2020 12:45:12

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2020-12-06T07:45:08', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '873512b2-b2b8-4af1-ba14-b890661a781e' User entered '06 Dec 2020 07:45:08'	System	06 Dec 2020 12:45:12
	System	06 Dec 2020 12:45:12

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '06 Dec 2020 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '10 Dec 2020 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2020-12-13T05:41:25', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7cfdc97a-45c8-4ff4-918a-7274b3106769'	System	13 Dec 2020 10:41:40
User entered 'No (N)'	System	13 Dec 2020 10:41:40

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2020-12-13T05:41:31', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7cfdc97a-45c8-4ff4-918a-7274b3106769'	System	13 Dec 2020 10:41:40
User entered 'No (N)'	System	13 Dec 2020 10:41:40

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2020-12-13T05:41:37', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '7cfd97a-45c8-4ff4-918a-7274b3106769'	System	13 Dec 2020 10:41:40
User entered '13 Dec 2020 05:41:37'	System	13 Dec 2020 10:41:40

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '13 Dec 2020 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '17 Dec 2020 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2020-12-20T16:11:01', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '5b992646-c07c-42b1-af17-e60a80e9eede'	System	20 Dec 2020 21:11:28
User entered 'No (N)'	System	20 Dec 2020 21:11:28

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2020-12-20T16:11:06', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '5b992646-c07c-42b1-af17-e60a80e9eede'	System	20 Dec 2020 21:11:28
User entered 'No (N)'	System	20 Dec 2020 21:11:28

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2020-12-20T16:11:24', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '5b992646-c07c-42b1-af17-e60a80e9eede' User entered '20 Dec 2020 16:11:24'	System	20 Dec 2020 21:11:28
	System	20 Dec 2020 21:11:28

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '20 Dec 2020 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '24 Dec 2020 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2020-12-27T06:51:21', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'eb7ac7a5-be55-4945-bc4f-491184b70c11'	System	27 Dec 2020 11:51:44
User entered 'No (N)'	System	27 Dec 2020 11:51:44

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2020-12-27T06:51:33', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'eb7ac7a5-be55-4945-bc4f-491184b70c11'	System	27 Dec 2020 11:51:44
User entered 'No (N)'	System	27 Dec 2020 11:51:44

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2020-12-27T06:51:40', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'eb7ac7a5-be55-4945-bc4f-491184b70c11'	System	27 Dec 2020 11:51:44
User entered '27 Dec 2020 06:51:40'	System	27 Dec 2020 11:51:44

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '27 Dec 2020 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '31 Dec 2020 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-01-06T09:17:29', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '4bc995bb-9fb0-404c-b7c0-9351feb7f442'	System	06 Jan 2021 14:17:41
User entered 'No (N)'	System	06 Jan 2021 14:17:41

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-01-06T09:17:34', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '4bc995bb-9fb0-404c-b7c0-9351feb7f442'	System	06 Jan 2021 14:17:41
User entered 'No (N)'	System	06 Jan 2021 14:17:41

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-06T09:17:37', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '4bc995bb-9fb0-404c-b7c0-9351feb7f442'	System	06 Jan 2021 14:17:41
User entered '06 Jan 2021 09:17:37'	System	06 Jan 2021 14:17:41

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '03 Jan 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '07 Jan 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-01-10T13:55:01', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '950f1b7e-0574-4579-9072-3fabaaddbd7c'	System	10 Jan 2021 18:55:22
User entered 'No (N)'	System	10 Jan 2021 18:55:22

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-01-10T13:55:12', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '950f1b7e-0574-4579-9072-3fabaaddbd7c'	System	10 Jan 2021 18:55:22
User entered 'No (N)'	System	10 Jan 2021 18:55:22

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-10T13:55:17', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '950f1b7e-0574-4579-9072-3fabaaddbd7c' User entered '10 Jan 2021 13:55:17'	System	10 Jan 2021 18:55:22

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '10 Jan 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '14 Jan 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-01-17T07:39:59', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '39425bb3-2005-4ab0-afa3-07853a2b212e'	System	17 Jan 2021 12:40:14
User entered 'No (N)'	System	17 Jan 2021 12:40:14

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-01-17T07:40:08', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '39425bb3-2005-4ab0-afa3-07853a2b212e'	System	17 Jan 2021 12:40:14
User entered 'No (N)'	System	17 Jan 2021 12:40:14

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-17T07:40:11', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '39425bb3-2005-4ab0-afa3-07853a2b212e' User entered '17 Jan 2021 07:40:11'	System	17 Jan 2021 12:40:14
	System	17 Jan 2021 12:40:14

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '17 Jan 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '21 Jan 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '24 Jan 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '28 Jan 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-01-31T12:02:18', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered 'Yes (Y)'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-01-31T12:02:25', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered 'No (N)'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-01-31T12:02:41', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered 'Yes (Y)'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '1'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Chills](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '1'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Cough](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Shortness of breath](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Difficulty breathing](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Fatigue](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Muscle aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Body aches](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Headache](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[New loss of taste](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[New loss of smell](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Sore throat](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Congestion](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Runny nose](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Nausea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Vomiting](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Diarrhea](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:03:14', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '0'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Please 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 (8b1ba14bae57953d)', Time: '2021-01-31T12:03:27', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-01-31T12:03:37', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered 'Yes (Y)'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Please 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 (8b1ba14bae57953d)', Time: '2021-01-31T12:03:44', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-01-31T12:04:07', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '2acd540b-cc7f-4ec8-bcbf-aa5928f14afc'	System	31 Jan 2021 17:07:21
User entered '31 Jan 2021 12:04:07'	System	31 Jan 2021 17:07:21

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '31 Jan 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '04 Feb 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-02-07T07:15:55', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd5241865-4c32-4a75-b8bf-6c12cf884d17'	System	07 Feb 2021 12:16:16
User entered 'No (N)'	System	07 Feb 2021 12:16:16

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-02-07T07:16:01', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd5241865-4c32-4a75-b8bf-6c12cf884d17'	System	07 Feb 2021 12:16:16
User entered 'No (N)'	System	07 Feb 2021 12:16:16

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-02-07T07:16:10', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'd5241865-4c32-4a75-b8bf-6c12cf884d17'	System	07 Feb 2021 12:16:16
User entered '07 Feb 2021 07:16:10'	System	07 Feb 2021 12:16:16

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '07 Feb 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '11 Feb 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-02-15T14:13:47', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b9734451-9810-44f9-bfc7-b0e01d1d9a9f'	System	15 Feb 2021 19:14:00
User entered 'No (N)'	System	15 Feb 2021 19:14:00

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-02-15T14:13:51', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b9734451-9810-44f9-bfc7-b0e01d1d9a9f'	System	15 Feb 2021 19:14:00
User entered 'No (N)'	System	15 Feb 2021 19:14:00

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-02-15T14:13:55', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'b9734451-9810-44f9-bfc7-b0e01d1d9a9f'	System	15 Feb 2021 19:14:00
User entered '15 Feb 2021 14:13:55'	System	15 Feb 2021 19:14:00

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '14 Feb 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '18 Feb 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-02-21T05:01:19', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '89c4c37e-1ae0-4544-9565-5d8e56fbc06c'	System	21 Feb 2021 10:01:40
User entered 'No (N)'	System	21 Feb 2021 10:01:40

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-02-21T05:01:26', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '89c4c37e-1ae0-4544-9565-5d8e56fbc06c'	System	21 Feb 2021 10:01:40
User entered 'No (N)'	System	21 Feb 2021 10:01:40

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-02-21T05:01:32', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '89c4c37e-1ae0-4544-9565-5d8e56fbc06c'	System	21 Feb 2021 10:01:40
User entered '21 Feb 2021 05:01:32'	System	21 Feb 2021 10:01:40

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '21 Feb 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '25 Feb 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-02-28T05:08:51-05:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '6ac2de09-7b4e-4416-a051-2abdc4354392'	System	28 Feb 2021 10:09:02
User entered 'No (N)'	System	28 Feb 2021 10:09:02

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-02-28T05:08:53-05:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '6ac2de09-7b4e-4416-a051-2abdc4354392'	System	28 Feb 2021 10:09:02
User entered 'No (N)'	System	28 Feb 2021 10:09:02

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-02-28T05:08:57-05:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '6ac2de09-7b4e-4416-a051-2abdc4354392' User entered '28 Feb 2021 05:08:57'	System	28 Feb 2021 10:09:02
	System	28 Feb 2021 10:09:02

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '28 Feb 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '04 Mar 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-03-07T12:54:14-05:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '5b09df5c-5bf4-4800-827c-2a9c85ba4300'	System	07 Mar 2021 17:54:27
User entered 'No (N)'	System	07 Mar 2021 17:54:27

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-03-07T12:54:23-05:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '5b09df5c-5bf4-4800-827c-2a9c85ba4300'	System	07 Mar 2021 17:54:27
User entered 'No (N)'	System	07 Mar 2021 17:54:27

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-03-07T12:54:27-05:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '5b09df5c-5bf4-4800-827c-2a9c85ba4300'	System	07 Mar 2021 17:54:27
User entered '07 Mar 2021 12:54:27'	System	07 Mar 2021 17:54:27

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '07 Mar 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '11 Mar 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-03-14T05:08:17-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '029d6b3e-7673-4e0d-a093-84cc694b9ac8'	System	14 Mar 2021 09:08:26
User entered 'No (N)'	System	14 Mar 2021 09:08:26

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-03-14T05:08:19-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '029d6b3e-7673-4e0d-a093-84cc694b9ac8'	System	14 Mar 2021 09:08:26
User entered 'No (N)'	System	14 Mar 2021 09:08:26

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-03-14T05:08:24-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '029d6b3e-7673-4e0d-a093-84cc694b9ac8'	System	14 Mar 2021 09:08:26
User entered '14 Mar 2021 05:08:24'	System	14 Mar 2021 09:08:26

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '14 Mar 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '18 Mar 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-03-21T05:40:41-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9fe9af57-43c2-40a1-9171-159f01bcae25'	System	21 Mar 2021 09:40:53
User entered 'No (N)'	System	21 Mar 2021 09:40:53

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-03-21T05:40:46-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9fe9af57-43c2-40a1-9171-159f01bcae25'	System	21 Mar 2021 09:40:53
User entered 'No (N)'	System	21 Mar 2021 09:40:53

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-03-21T05:40:49-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '9fe9af57-43c2-40a1-9171-159f01bcae25'	System	21 Mar 2021 09:40:53
User entered '21 Mar 2021 05:40:49'	System	21 Mar 2021 09:40:53

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '21 Mar 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '25 Mar 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-03-28T08:20:56-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '63bcc3ec-a96e-48b7-a3ed-f4fe62679f2b'	System	28 Mar 2021 12:21:10
User entered 'No (N)'	System	28 Mar 2021 12:21:10

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-03-28T08:21:01-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '63bcc3ec-a96e-48b7-a3ed-f4fe62679f2b'	System	28 Mar 2021 12:21:10
User entered 'No (N)'	System	28 Mar 2021 12:21:10

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-03-28T08:21:05-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '63bcc3ec-a96e-48b7-a3ed-f4fe62679f2b' User entered '28 Mar 2021 08:21:05'	System	28 Mar 2021 12:21:10
	System	28 Mar 2021 12:21:10

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '28 Mar 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '01 Apr 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-04-08T08:18:03-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '87e1aec7-040f-4a8b-9c86-afd681d00cf9' User entered 'No (N)'	System	08 Apr 2021 12:18:13
	System	08 Apr 2021 12:18:13

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-04-08T08:18:06-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '87e1aec7-040f-4a8b-9c86-afd681d00cf9'	System	08 Apr 2021 12:18:13
User entered 'No (N)'	System	08 Apr 2021 12:18:13

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-04-08T08:18:10-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '87e1aec7-040f-4a8b-9c86-afd681d00cf9'	System	08 Apr 2021 12:18:13
User entered '08 Apr 2021 08:18:10'	System	08 Apr 2021 12:18:13

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '04 Apr 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '08 Apr 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-04-11T07:38:20-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '39fd5fbf-b046-4bab-abc6-fcc005d24997'	System	11 Apr 2021 11:38:36
User entered 'No (N)'	System	11 Apr 2021 11:38:36

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-04-11T07:38:24-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '39fd5fbf-b046-4bab-abc6-fcc005d24997'	System	11 Apr 2021 11:38:36
User entered 'No (N)'	System	11 Apr 2021 11:38:36

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-04-11T07:38:33-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '39fd5fbf-b046-4bab-abc6-fcc005d24997'	System	11 Apr 2021 11:38:36
User entered '11 Apr 2021 07:38:33'	System	11 Apr 2021 11:38:36

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '11 Apr 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '15 Apr 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-04-18T07:30:46-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1b9ba266-8ac4-4e19-b425-b73bfb9c1cb8' User entered 'No (N)'	System	18 Apr 2021 11:30:57
	System	18 Apr 2021 11:30:57

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-04-18T07:30:50-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1b9ba266-8ac4-4e19-b425-b73bfb9c1cb8'	System	18 Apr 2021 11:30:57
User entered 'No (N)'	System	18 Apr 2021 11:30:57

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-04-18T07:30:54-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '1b9ba266-8ac4-4e19-b425-b73bfb9c1cb8'	System	18 Apr 2021 11:30:57
User entered '18 Apr 2021 07:30:54'	System	18 Apr 2021 11:30:57

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '18 Apr 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '22 Apr 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[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 (8b1ba14bae57953d)', Time: '2021-04-25T05:31:44-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a1b4084b-4cc6-4650-912d-88ed940d811b'	System	25 Apr 2021 09:31:55
User entered 'No (N)'	System	25 Apr 2021 09:31:55

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

Have you been exposed to someone with 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 (8b1ba14bae57953d)', Time: '2021-04-25T05:31:47-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a1b4084b-4cc6-4650-912d-88ed940d811b'	System	25 Apr 2021 09:31:55
User entered 'No (N)'	System	25 Apr 2021 09:31:55

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-04-25T05:31:52-04:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: 'a1b4084b-4cc6-4650-912d-88ed940d811b'	System	25 Apr 2021 09:31:55
User entered '25 Apr 2021 05:31:52'	System	25 Apr 2021 09:31:55

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '25 Apr 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '29 Apr 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '02 May 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '06 May 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '09 May 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '13 May 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '16 May 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '20 May 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '23 May 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '27 May 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '30 May 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '03 Jun 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '06 Jun 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '10 Jun 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '13 Jun 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '17 Jun 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '20 Jun 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '24 Jun 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '27 Jun 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '01 Jul 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '04 Jul 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '08 Jul 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '11 Jul 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '15 Jul 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '18 Jul 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '22 Jul 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '25 Jul 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '29 Jul 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '01 Aug 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '05 Aug 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '08 Aug 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '12 Aug 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '15 Aug 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '19 Aug 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '22 Aug 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '26 Aug 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '29 Aug 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '02 Sep 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '05 Sep 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '09 Sep 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '12 Sep 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '16 Sep 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '19 Sep 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '23 Sep 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '26 Sep 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '30 Sep 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '03 Oct 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '07 Oct 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '10 Oct 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '14 Oct 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '17 Oct 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '21 Oct 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '24 Oct 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '28 Oct 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '31 Oct 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '04 Nov 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '07 Nov 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '11 Nov 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '14 Nov 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '18 Nov 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '21 Nov 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '25 Nov 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '28 Nov 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '02 Dec 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '05 Dec 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '09 Dec 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '12 Dec 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '16 Dec 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '19 Dec 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '23 Dec 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '26 Dec 2021 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '30 Dec 2021 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '02 Jan 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '06 Jan 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '09 Jan 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '13 Jan 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '16 Jan 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '20 Jan 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '23 Jan 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '27 Jan 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '30 Jan 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '03 Feb 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '06 Feb 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '10 Feb 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '13 Feb 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '17 Feb 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '20 Feb 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '24 Feb 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '27 Feb 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '03 Mar 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '06 Mar 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '10 Mar 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '13 Mar 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '17 Mar 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '20 Mar 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '24 Mar 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '27 Mar 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '31 Mar 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '03 Apr 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '07 Apr 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '10 Apr 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '14 Apr 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '17 Apr 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '21 Apr 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '24 Apr 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '28 Apr 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '01 May 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '05 May 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '08 May 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '12 May 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '15 May 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '19 May 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '22 May 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '26 May 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '29 May 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '02 Jun 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '05 Jun 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '09 Jun 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '12 Jun 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '16 Jun 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '19 Jun 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '23 Jun 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '26 Jun 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '30 Jun 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '03 Jul 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '07 Jul 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '10 Jul 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '14 Jul 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '17 Jul 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '21 Jul 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '24 Jul 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '28 Jul 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '31 Jul 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '04 Aug 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '07 Aug 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '11 Aug 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '14 Aug 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '18 Aug 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '21 Aug 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '25 Aug 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '28 Aug 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '01 Sep 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '04 Sep 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '08 Sep 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '11 Sep 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '15 Sep 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '18 Sep 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '22 Sep 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '25 Sep 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '29 Sep 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '02 Oct 2022 00:01'	System	19 Nov 2020 10:54:46

US3412067

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:29:16

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 10:54:46
Amendment Manager: User entered '06 Oct 2022 23:59'	System	19 Nov 2020 10:54:46

US3412067

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:29:16

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-02-28T05:09:12-05:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '214ca020-8e25-452e-8b5f-1b3fe502f100'	System	28 Feb 2021 10:09:22
User entered 'No (N)'	System	28 Feb 2021 10:09:22

US3412067

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:29:16

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 07:18:14
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (8b1ba14bae57953d)', Time: '2021-02-28T05:09:18-05:00', User OID: 'PatientReportedOutcome (US3412067)', ODM File OID: '214ca020-8e25-452e-8b5f-1b3fe502f100'	System	28 Feb 2021 10:09:22
User entered '28 Feb 2021 05:09:18'	System	28 Feb 2021 10:09:22

US3412067

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:18:10

US3412067

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:55
User entered '23 Oct 2020'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:18:10

US3412067

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:55
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:18:10

US3412067

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:55
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:18:10

US3412067

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:28:55
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Oct 2020 13:19:20

US3412067

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:18:32
User entered 'I'	System	23 Oct 2020 13:19:20

US3412067

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Dec 2020 15:44:30

US3412067

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '25 Nov 2020'	Mason Urban (b) (4)	28 Dec 2020 15:44:30

US3412067

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	28 Dec 2020 15:44:30

US3412067

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Mason Urban (b) (4)	28 Dec 2020 15:44:30

US3412067

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Dec 2020 15:44:36

US3412067

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User entered 'I'	System	28 Dec 2020 15:44:36

US3412067

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Dec 2020 15:44:45

US3412067

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '28 Dec 2020'	Mason Urban (b) (4)	28 Dec 2020 15:44:45

US3412067

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	28 Dec 2020 15:44:45

US3412067

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Mason Urban (b) (4)	28 Dec 2020 15:44:45

US3412067

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Mason Urban (b) (4)	28 Dec 2020 15:44:50

US3412067

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User entered 'I'	System	28 Dec 2020 15:44:50

US3412067

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Mason Urban (b) (4)	19 Feb 2021 19:20:43

US3412067

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '25 Jan 2021'	Mason Urban (b) (4)	19 Feb 2021 19:20:43

US3412067

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	19 Feb 2021 19:20:43

US3412067

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Mason Urban (b) (4)	19 Feb 2021 19:20:43

US3412067

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Mason Urban (b) (4)	19 Feb 2021 19:20:49

US3412067

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 01:52:30
User entered 'I'	System	19 Feb 2021 19:20:49

US3412067

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User closed query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 02-Mar-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 09:56:52
Query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 02-Mar-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' answered with 'this sample was collected under ol day 1 visit. it was a combination visit. All lab results have been received' (Site from DM).	Steven Anderson (b) (4) (b) (4)	31 Mar 2021 14:22:53
User opened query 'Per GCL Lab Reconciliation: Central Nasopharyngeal Swab(Single): Sample dated 02-Mar-2021 is reported under OL-D1 visit in PPD Central lab, however the same is missing in EDC under Participant Decision Visit OL-D1(1).Please review if the sample has been collected and then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	19 Mar 2021 11:34:11
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	11 Mar 2021 13:49:47

US3412067

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User closed query 'Per GCL Lab recon: Immunogenicity: PPD has Immuno sample dated 02MAR2021 Barcode: 1F602229873 labelled as OL-D1, however data is missing in EDC. If this visit is overlapping with Visit 4 then per CCG, the data needs to be recorded on both the visit. Please review the Preclarus and record the data in the Missing data on the OL visit. Thank you.' (Site from DM). User signature succeeded.	(b) (4)	19 Apr 2021 14:30:20
Query 'Per GCL Lab recon: Immunogenicity: PPD has Immuno sample dated 02MAR2021 Barcode: 1F602229873 labelled as OL-D1, however data is missing in EDC. If this visit is overlapping with Visit 4 then per CCG, the data needs to be recorded on both the visit. Please review the Preclarus and record the data in the Missing data on the OL visit. Thank you.' answered with 'this sample was collected under ol day 1 visit. it was a combination visit. All lab results have been received' (Site from DM). User opened query 'Per GCL Lab recon: Immunogenicity: PPD has Immuno sample dated 02MAR2021 Barcode: 1F602229873 labelled as OL-D1, however data is missing in EDC. If this visit is overlapping with Visit 4 then per CCG, the data needs to be recorded on both the visit. Please review the Preclarus and record the data in the Missing data on the OL visit. Thank you.' (Site from DM). User entered '02 Mar 2021'	Richard Powell (b) (4) (b) (4) Steven Anderson (b) (4) (b) (4) (b) (4), (b) (6) Andrea Newlands (b) (4) (b) (4)	16 Apr 2021 14:09:27 31 Mar 2021 14:23:06 23 Mar 2021 14:26:46 11 Mar 2021 13:49:47

US3412067

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[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 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	11 Mar 2021 13:49:47

US3412067

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'VISIT4'	System	11 Mar 2021 13:49:47

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'No (N)'	Andrea Newlands (b) (4)	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Andrea Newlands (b) (4)	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered empty.	System	30 Mar 2021 13:13:45

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10

US3412067

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:29:16

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10

US3412067

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:16

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'No (N)'	Andrea Newlands (b) (4)	11 Mar 2021 13:49:52

US3412067

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:29:16

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered empty.	Andrea Newlands (b) (4)	11 Mar 2021 13:49:52

US3412067

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	11 Mar 2021 13:50:13

US3412067

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User closed query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	11 Mar 2021 13:51:42
Query 'The Collection Date is not equal to Visit Date. System Please review and reconcile.' answered by data change (Site from System).	System	11 Mar 2021 13:51:42
User entered '02 Mar 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	11 Mar 2021 13:51:42
User opened query 'The Collection Date is not equal to Visit Date. Please review and reconcile.' (Site from System).	(b) (4)	11 Mar 2021 13:50:13
User entered '10 Mar 2021'	System	11 Mar 2021 13:50:13
	Andrea Newlands (b) (4)	11 Mar 2021 13:50:13
	(b) (4)	

US3412067

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '08:01'	Andrea Newlands (b) (4)	11 Mar 2021 13:50:13

US3412067

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered '02 Mar 2021 08:01'	System	11 Mar 2021 13:51:42
User entered '10 Mar 2021 08:01'	System	11 Mar 2021 13:50:13

US3412067

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	11 Mar 2021 13:52:16

US3412067

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 11:53:10
User entered 'I'	System	11 Mar 2021 13:52:16

US3412067

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:11:21

US3412067

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '29 Mar 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:11:21

US3412067

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Contact Not Made (CONTACT NOT MADE)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 18:11:21

US3412067

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:29:16

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'PHONE NOT RINGING 29 MAR 2021. Contact made 30 MAR 2021.' reason for change: Data Entry Error	(b) (4), (b) (6)	30 Mar 2021 21:01:20
User entered 'phone not ringing'		29 Mar 2021 18:11:21

US3412067

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	30 Mar 2021 21:01:24

US3412067

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:29:16

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	30 Mar 2021 21:01:24

US3412067

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

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 19:22:48

US3412067

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

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '2 Mar 2021'	Steven Anderson (b) (4)	31 Mar 2021 19:22:48

US3412067

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

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

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 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	31 Mar 2021 19:22:48

US3412067

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

Form: Visit Date

Generated On: 09 Jun 2021 17:29:16

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered 'UNBLND_DECIDE'	System	31 Mar 2021 19:22:48

US3412067

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:16

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '2 Mar 2021'	Steven Anderson (b) (4)	31 Mar 2021 19:23:03

US3412067

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:16

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '0'	Steven Anderson (b) (4)	31 Mar 2021 19:23:03

US3412067

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:16

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 19:23:03

US3412067

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:16

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Amendment 6 or later (Amendment 6 or later)'	Steven Anderson (b) (4)	31 Mar 2021 19:23:03

US3412067

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:16

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '2 Mar 2021'	Steven Anderson (b) (4)	31 Mar 2021 19:23:03

US3412067

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:16

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'mRNA-1273 (mRNA-1273)'	Steven Anderson (b) (4)	31 Mar 2021 19:23:03

US3412067

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:16

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'mRNA-1273 (mRNA-1273)'	Steven Anderson (b) (4)	31 Mar 2021 19:23:03

US3412067

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:16

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'mRNA-1273 (mRNA-1273)'	Steven Anderson (b) (4)	31 Mar 2021 19:23:03

US3412067

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:16

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'No (N)'	Steven Anderson (b) (4)	31 Mar 2021 19:23:03

US3412067

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:16

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered empty.	System	31 Mar 2021 19:23:03

US3412067

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

Form: Unblinding

Generated On: 09 Jun 2021 17:29:16

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered empty.	System	31 Mar 2021 19:23:03

US3412067

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 19:26:40

US3412067

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '2 Mar 2021'	Steven Anderson (b) (4)	31 Mar 2021 19:26:40

US3412067

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '08:01'	Steven Anderson (b) (4)	31 Mar 2021 19:26:40

US3412067

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered '2 Mar 2021 08:01'	System	31 Mar 2021 19:26:40

US3412067

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:29:16

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 19:26:51

US3412067

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:29:16

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '2 Mar 2021'	Steven Anderson (b) (4)	31 Mar 2021 19:26:51

US3412067

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:29:16

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '08:03'	Steven Anderson (b) (4)	31 Mar 2021 19:26:51

US3412067

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	28 Apr 2021 20:45:23
User entered '2 Mar 2021 08:03'	System	31 Mar 2021 19:26:51

US3412067

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:29:16

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:26
User closed query 'Per DM CLR: Per Safety Follow Up Diary Day 187, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).		13 Apr 2021 12:17:35
Query 'Per DM CLR: Per Safety Follow Up Diary Day 187, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' answered with 'subject received back surgery for the existing ae of ongoing osteoarthritis.' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 15:09:56
User opened query 'Per DM CLR: Per Safety Follow Up Diary Day 187, 'Experienced any new COVID-19 symptoms since last questionnaire or study contact?'; and 'Have you contacted a healthcare provider since last questionnaire or study contact?' = Yes, however, please note that there is no corresponding AE for this recorded data within this timeframe. Please reconcile and update to record the AE as applicable, otherwise provide clarification. ' (Site from DM).	(b) (4), (b) (6)	26 Mar 2021 18:13:45
User signature succeeded.	Richard Powell (b) (4) (b) (4)	15 Mar 2021 15:27:49
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	05 Feb 2021 17:54:26

US3412067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[AEID](#)

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	12 Apr 2021 13:54:34
DataPoint Verified.		23 Feb 2021 22:48:36
User entered 'USA-US061-2021-mRNA-1273-P301000008'	System	08 Feb 2021 15:59:47
User entered 'New'	(b) (4), (b) (6)	08 Feb 2021 15:59:47

US3412067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:48:35
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Infections NEC, PT: Post procedural infection, LLT: Postoperative infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 00:14:47
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Feb 2021 00:14:47
Data point term sent to Coder	System	05 Feb 2021 17:58:40
User entered 'Post-op infection'	Steven Anderson (b) (4) (b) (4)	05 Feb 2021 17:58:08

US3412067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:48:38
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

US3412067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:48:40
User entered 'No (N)'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

US3412067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:48:42
User entered 'No (N)'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:48:44
User entered '02 Feb 2021'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

US3412067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:49:00
User entered empty.	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:48:49
User entered 'Yes (Y)'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:49:07
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4)	11 Feb 2021 16:14:24
	Steven Anderson (b) (4) (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:49:02
User entered empty.	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:49:04
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

US3412067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:49:13
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this serious condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' canceled (Site from DM).		17 Feb 2021 15:54:39
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this serious condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).		17 Feb 2021 15:54:14
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	05 Feb 2021 17:58:08

US3412067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:49:16
User entered '0'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

US3412067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:49:18
User entered '0'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

US3412067

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[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)	26 Apr 2021 18:32:35
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'hospital admission date has been updated. Site has requested medical records three times. Will update discharge date as soon as records are received.' (Site from System).		22 Apr 2021 13:27:43
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		12 Apr 2021 13:55:09
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'discharge summary will be provided when site receives medical records from hospital' (Site from Safety).	Steven Anderson (b) (4)	09 Apr 2021 19:49:08
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:49:25
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		11 Feb 2021 16:15:39
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	05 Feb 2021 17:58:08
User entered '1'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:49:27
User entered '02 Feb 2021'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		11 Feb 2021 16:14:11
User entered empty.	Steven Anderson (b) (4) (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	09 Apr 2021 19:48:39
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).		09 Apr 2021 19:48:39
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	09 Apr 2021 19:48:39
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)	
User entered 'Unknown (UNK)'	System	05 Feb 2021 17:58:08
	Steven Anderson (b) (4)	05 Feb 2021 17:58:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered empty.	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered '0'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered '0'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered '0'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:55:26
User closed query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).		12 Apr 2021 13:55:30
Query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	09 Apr 2021 14:39:07
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	(b) (4)	17 Feb 2021 17:00:10
User opened query 'PV Query: Since the subject received at least one dose of study drug before this event started, the relationship to investigational product/study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:15:05
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:55:49
User closed query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	12 Apr 2021 13:55:47
Query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	(b) (4) 09 Apr 2021 14:43:25
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	(b) (4) 17 Feb 2021 17:00:10
User opened query 'PV Query: Study procedure refers to the information outlined in the protocol and whether something like the administration technique or some part of the protocol could be causative of this event. Since the subject received the study drug this should be Related or Not Related. Please update accordingly.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:15:15
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4) (b) (4)	(b) (4) 05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:59:22
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User opened query 'Per CDM RQ: Thank you for your response. Please keep query open until updates have been made. Thank you!' (Site from DM).	(b) (4), (b) (6)	25 Apr 2021 16:27:00
User closed query 'Per CDM re-query: Previous response states updated and Con Med is now checked, however there is no corresponding medication recorded. Please review and update as appropriate.' (Site from DM).		25 Apr 2021 16:27:00
Query 'Per CDM re-query: Previous response states updated and Con Med is now checked, however there is no corresponding medication recorded. Please review and update as appropriate.' answered with 'conmeds not yet available but will be updated once medical records are received' (Site from DM).		
User opened query 'Per CDM re-query: Previous response states updated and Con Med is now checked, however there is no corresponding medication recorded. Please review and update as appropriate.' (Site from DM).	Andrea Newlands (b) (4)	16 Apr 2021 16:50:15
User closed query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this serious condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 12:28:57
User closed query 'please uncheck None and Check concomitant medications as per source' (Site from CRA).		09 Apr 2021 18:00:02
Query 'please uncheck None and Check concomitant medications as per source' answered with 'updated' (Site from CRA).		
Query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this serious condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	09 Apr 2021 14:44:26
User entered '0' reason for change: Data Entry Error	Andrea Newlands (b) (4)	09 Apr 2021 14:44:11

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

None

Audit	User	Time (GMT)
User opened query 'please uncheck None and Check concomitant medications as per source' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 22:51:28
User opened query 'Per DM CLR: Please note that there is no Con Med listed for treatment of this serious condition and treatment would be expected. Please review and if applicable add a Con Med or a therapeutic Con Proc or provide an explanation for no treatment.' (Site from DM).		17 Feb 2021 15:55:02
User entered 'I'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08
	(b) (4)	

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
Query 'per source on antibiotics - please update to yes and add to Con Med CRF when medical records available' canceled (Site from CRA).		19 Apr 2021 16:56:19
User entered '1' reason for change: Data Entry Error	Andrea Newlands (b) (4)	09 Apr 2021 14:44:11
User opened query 'per source on antibiotics - please update to yes and add to Con Med CRF when medical records available' (Site from CRA).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 22:50:58
User entered '0'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered '0'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		11 Feb 2021 16:14:33
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4) (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered empty.	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered 'SUBJECT RETURNED SITES VOICEMAIL AND STATED THAT HE WAS IN HOSPITAL DUE TO AN INFECTION FROM HIS BACK SURGERY. SUBJECT HAD ORIGINAL BACK SURGERY ON 05-JAN-2021. THIS WAS A PLANNED PROCEDURE DUE TO HIS OA OF THE BACK. SUBJECT HAD A FOLLOW UP SURGERY ON 08-JAN-2021 THAT WAS ALSO PLANNED. HOWEVER STARTING ON 02-FEB-2021 SUBJECT DEVELOPED A POST-OP INFECTION THAT HOSPITALIZED HIM ON THE SAME DAY. SUBJECT IS BEING TREATED WITH ANTI-BIOTICS AND STILL CURRENTLY IN HOSPITAL. SITE WILL REQUEST MEDICAL RECORDS FOR FURTHER INFORMATION.'	Andrea Newlands (b) (4)	09 Apr 2021 15:09:08
reason for change: Data Entry Error		
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. If needed, results with patient identifiers redacted and subject ID added can be sent to Safety_Moderna@iqvia.com or fax to 866.599.1342. If no results are available, please confirm in your response.' (Site from Safety).	(b) (4), (b) (6)	11 Feb 2021 16:15:26
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).		11 Feb 2021 16:14:52
User opened query 'PV Query: Please specify the antibiotics given to the subject for the event as treatment and enter the same in concomitant section of the eCRF.' (Site from Safety).		11 Feb 2021 16:14:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Subject returned sites voicemail and stated that he was in hospital due to an infection from his back surgery. Subject had original back surgery on 03-Jan-2021. this was a planned procedure due to his OA of the back. Subject had a follow up surgery on 08-Jan-2021 that was also planned. However starting on 02-Feb-2021 subject developed a post-op infection that hospitalized him on the same day. Subject is being treated with anti-biotics and still currently in hospital. Site will request medical records for further information.'	Steven Anderson (b) (4)	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:29:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	05 Feb 2021 17:58:08

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered 'USA-US061-2021-mRNA-1273-P301000008'		18 Feb 2021 20:26:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 15:08:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 15:08:02
DataPoint Verified.	(b) (4), (b) (6)	19 Apr 2021 14:25:05
User closed query 'please consider adding back to the event term' (Site from CRA).		19 Apr 2021 14:18:51
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Osteoarthritis of lumbar spine - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:27:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	11 Apr 2021 19:27:34
Data point term sent to Coder	System	09 Apr 2021 14:50:02
Query 'please consider adding back to the event term' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 14:49:17
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 14:49:11
Coding entries removed.	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 14:49:11
User entered 'PROGRESSIVE/WORSENING OSTEOARTHRITIS - back' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 14:49:11
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 18:25:02
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 18:25:02
User opened query 'please consider adding back to the event term' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 22:48:23
DataPoint Verified.		23 Feb 2021 22:41:36
Data point term sent to Coder	System	17 Feb 2021 17:05:36
User entered 'Progressive/worsening osteoarthritis'	Steven Anderson (b) (4) (b) (4)	17 Feb 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:41:39
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:41:41
User entered 'No (N)'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:41:43
User entered 'No (N)'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'This is date of first surgery, but it is planned surgery so start date should be date when decided surgery was needed? Please review source/hospital records when available and update accordingly' (Site from CRA). DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:09:45
		20 Apr 2021 17:09:13
Query 'This is date of first surgery, but it is planned surgery so start date should be date when decided surgery was needed? Please review source/hospital records when available and update accordingly' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	09 Apr 2021 14:49:46
User entered '01 Nov 2020' reason for change: Data Entry Error	(b) (4)	09 Apr 2021 14:49:40
User opened query 'This is date of first surgery, but it is planned surgery so start date should be date when decided surgery was needed? Please review source/hospital records when available and update accordingly' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 22:45:45
User entered '3 Jan 2021'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07
	(b) (4)	

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:45:51
User entered empty.	Steven Anderson (b) (4)	17 Feb 2021 17:05:07
	(b) (4)	

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:45:49
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User opened query 'PV Query: Please provide the event end dates (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available.' (Site from Safety). User entered empty.	(b) (4)	24 Feb 2021 16:06:05
	Steven Anderson (b) (4) (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered empty.	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:00
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07
	(b) (4)	

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:01
User entered 'Yes (Y)'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered '0'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered '0'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:15
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). User entered '1'	System	17 Feb 2021 17:05:07
	Steven Anderson (b) (4)	17 Feb 2021 17:05:07
	(b) (4)	

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:20
User entered '3 Jan 2021'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User opened query 'PV Query: Please provide the hospital discharge date for the event progressive/worsening osteoarthritis.' (Site from Safety).		24 Feb 2021 16:05:34
User entered empty.	Steven Anderson (b) (4) (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:25
User entered 'No (N)'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:38
User entered empty.	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:40
User entered '0'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:42
User entered '0'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:44
User entered '0'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:53
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:55
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	23 Feb 2021 22:46:57
User entered 'Not Applicable (NOT APPLICABLE)'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[None](#)

Audit	User	Time (GMT)
User closed query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). DataPoint Verified.	System	09 Apr 2021 14:51:30
	(b) (4), (b) (6)	23 Feb 2021 22:47:04
User opened query 'Other action taken is missing. Please check at least one action from the options provided.' (Site from System). User entered '0'	System	17 Feb 2021 17:05:07
	Steven Anderson (b) (4)	17 Feb 2021 17:05:07
	(b) (4)	

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered '0'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Please add surgeries on 03 Jan 2021 and 08 Jan 2021 to Con Procedures CRF' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:12:54
DataPoint Verified.		20 Apr 2021 17:12:31
Query 'Please add surgeries on 03 Jan 2021 and 08 Jan 2021 to Con Procedures CRF' answered with 'surgeries have been added on con procedure list' (Site from CRA).	Steven Anderson (b) (4)	09 Apr 2021 19:47:02
User entered '1' reason for change: Data Entry Error	Andrea Newlands (b) (4)	09 Apr 2021 14:51:30
User opened query 'Please add surgeries on 03 Jan 2021 and 08 Jan 2021 to Con Procedures CRF' (Site from CRA).	(b) (4), (b) (6)	23 Feb 2021 22:41:00
User entered '0'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User opened query 'PV Query: Please provide the final event outcomes, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved.' (Site from Safety).		24 Feb 2021 16:06:30
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4) (b) (4)	17 Feb 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User entered empty.	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	29 Apr 2021 15:35:39
User closed query 'Per source, surgeries on 05 Jan 2021 and 08 Jan 2021. Please confirm and update surgery dates as appropriate' (Site from CRA).		23 Apr 2021 14:16:29
Query 'Per source, surgeries on 05 Jan 2021 and 08 Jan 2021. Please confirm and update surgery dates as appropriate' answered with 'Site is awaiting medical records to confirm these dates prior to updating any information. site will address once medical records are obtained.' (Site from CRA).	Steven Anderson (b) (4)	23 Apr 2021 14:08:33
User opened query 'Per source, surgeries on 05 Jan 2021 and 08 Jan 2021. Please confirm and update surgery dates as appropriate' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 17:14:22
DataPoint Un-verified.		20 Apr 2021 17:13:26
User closed query 'Per DM CLR: Narrative = SCHEDULED BACK SURGERY ON 03-JAN-2021 AND THEN A SECONDARY BACK SURGERY ON 08-JAN-2021. Please review and confirm if these were already performed. If yes, ensure that this is captured in the appropriate eCRF.'		13 Apr 2021 12:29:45
' (Site from DM).		
Query 'Per DM CLR: Narrative = SCHEDULED BACK SURGERY ON 03-JAN-2021 AND THEN A SECONDARY BACK SURGERY ON 08-JAN-2021. Please review and confirm if these were already performed. If yes, ensure that this is captured in the appropriate eCRF.'	Steven Anderson (b) (4)	09 Apr 2021 19:47:30
' answered with 'these were already performed and have been added to con procedure list' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Narrative = SCHEDULED BACK SURGERY ON 03-JAN-2021 AND THEN A SECONDARY BACK SURGERY ON 08-JAN-2021. Please review and confirm if these were already performed. If yes, ensure that this is captured in the appropriate eCRF.'	(b) (4), (b) (6)	01 Mar 2021 08:01:39
' (Site from DM).		
DataPoint Verified.		23 Feb 2021 22:47:29

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Narrative](#)

Audit	User	Time (GMT)
User entered 'Per PI's instructions this was to be a separated SAE from the post-op wound infection and be written up on its own. Subject had a worsening of their Osteoarthritis that required a scheduled back surgery on 03-Jan-2021 and then a secondary back surgery on 08-Jan-2021. Site is requesting medical records for additional information.'	Steven Anderson (b) (4)	17 Feb 2021 17:05:07

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Feb 2021 17:05:07

US3412067

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:29:16

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	17 Feb 2021 17:05:07

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:29:16

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:51
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	20 Aug 2020 20:38:44
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	07 Aug 2020 13:26:57
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	21 Aug 2020 06:24:19
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 06:24:19
Data point term sent to Coder	System	20 Aug 2020 20:40:56
User entered 'CYCLOBENZAPONE'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:40:12

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
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) (4), (b) (6)	15 Oct 2020 04:55:19
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 IF THIS WAS OSTEOARTHRITIS ' (Site from DM).	Mylene Asmar-Rios (b) (4)	02 Oct 2020 15:50:53
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 10:08:28
User entered 'NECK PAIN'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:40:12

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '10'	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'as needed (PRN)'	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:29:12
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	20 Aug 2020 20:40:12
User entered 'UN Apr 2020'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:40:12

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:40:12
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:40:12

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:40:12

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:40:12

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: ACETIC ACID DERIVATIVES AND RELATED SUBSTANCES, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 20:42:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:42:26
Data point term sent to Coder	System	20 Aug 2020 20:41:59
User entered 'DICLOFENAC'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:41:41

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'OA'	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '50'	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'as needed (PRN)'	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:29:12
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	20 Aug 2020 20:41:41
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:41:41

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:41:41
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:41:41

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:41:41

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	20 Aug 2020 20:41:41

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: ANTIDEPRESSANTS, ATC: OTHER ANTIDEPRESSANTS, PRODUCT: VENLAFAXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 20:47:21
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:47:21
Data point term sent to Coder	System	20 Aug 2020 20:46:08
User entered 'VENLAFAXINE'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:45:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered 'ANXIETY/DEPRESSION'	(b) (4) Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:45:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '150'	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:29:12
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	20 Aug 2020 20:45:20
User entered 'UN UNK 2018'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:45:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:45:20
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:45:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:45:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:45:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: THIAZOLIDINEDIONES, PRODUCT: PIOGLITAZONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 08:25:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 08:25:17
Data point term sent to Coder	System	20 Aug 2020 20:47:13
User entered 'PIOGLITAZONE'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:47:08

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'T2DM'	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '45'	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:29:12
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	20 Aug 2020 20:47:08
User entered 'UN UNK 2007'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:47:08

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:47:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:47:08

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:47:08

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:47:08

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: UROLOGICALS, ATC: DRUGS USED IN BENIGN PROSTATIC HYPERTROPHY, ATC: ALPHA-ADRENORECEPTOR ANTAGONISTS, PRODUCT: TAMSULOSIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	20 Aug 2020 20:50:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:50:22
Data point term sent to Coder	System	20 Aug 2020 20:49:17
User entered 'TAMSULOSIN'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:49:11

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'BPH'	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '.4'	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:29:12
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	20 Aug 2020 20:49:11
User entered 'UN Apr 2020'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:49:11

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:49:11
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:49:11

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:49:11

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:49:11

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 20:51:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:51:22
Data point term sent to Coder	System	20 Aug 2020 20:50:20
User entered 'ATORVASTATIN'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:50:08

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered 'HIGH CHOLESTEROL'	(b) (4) Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:50:08

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '10'	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:29:12
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	20 Aug 2020 20:50:08
User entered '15 Apr 2020'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:50:08

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:50:08
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:50:08

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:50:08

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:50:08

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ACE INHIBITORS, PLAIN, ATC: ACE INHIBITORS, PLAIN, PRODUCT: LISINOPRIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	20 Aug 2020 20:53:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	20 Aug 2020 20:53:22
Data point term sent to Coder	System	20 Aug 2020 20:52:26
User entered 'LISINOPRIL'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:51:44

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'HTN'	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '5'	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:51:44

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:29:12
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	20 Aug 2020 20:51:44
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:51:44

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:51:44
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:51:44

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:51:44

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:51:44

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: GLUCAGON-LIKE PEPTIDE-1 (GLP-1) ANALOGUES, PRODUCT: LIRAGLUTIDE, PRODUCTSYNONYM: VICTOZA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	21 Aug 2020 07:15:12
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 07:15:12
Data point term sent to Coder	System	20 Aug 2020 20:53:30
User entered 'VICTOZA'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:52:53

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:52:53
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'T2DM'	Mylene Asmar-Rios	20 Aug 2020 20:52:53
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '1.8'	Mylene Asmar-Rios	20 Aug 2020 20:52:53
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	20 Aug 2020 20:52:53
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:52:53
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:52:53

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered empty.	(b) (4) Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:52:53

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	20 Aug 2020 20:52:53
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:52:53
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	(b) (4)	21 Aug 2020 01:29:12
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	20 Aug 2020 20:52:53
User entered 'UN UNK 2012'	Mylene Asmar-Rios (b) (4)	20 Aug 2020 20:52:53

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	20 Aug 2020 20:52:53
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	20 Aug 2020 20:52:53
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	20 Aug 2020 20:52:53
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	20 Aug 2020 20:52:53
	(b) (4)	

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:52:53

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	20 Aug 2020 20:52:53

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	20 Aug 2020 20:52:53

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: VIRAL VACCINES, ATC: INFLUENZA VACCINES, PRODUCT: INFLUENZA VACCINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 18:39:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Dec 2020 18:39:20
Data point term sent to Coder	System	29 Dec 2020 18:38:17
User entered 'FLU VACCINE'	Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered 'Yes (Y)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered 'GENERAL HEALTH'	Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered '0.5'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered 'mL (mL)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered empty.	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered 'once (ONCE)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered empty.	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered 'Intramuscular (INTRAMUSCULAR)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered empty.	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered '05 Nov 2020'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered '0'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered '05 Nov 2020'	Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:13:51
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User entered empty.	System	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User entered empty.	System	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:59
User entered empty.	System	29 Dec 2020 18:38:13

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FIRST-GENERATION CEPHALOSPORINS, PRODUCT: CEFAZOLIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 15:57:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 15:57:08
Data point term sent to Coder	System	23 Apr 2021 15:48:49
User entered 'Cefazolin'	(b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '50'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'every 8 hours'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:48:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:01:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:01:02
Data point term sent to Coder	System	23 Apr 2021 15:50:50
User entered 'Oxycodone'	(b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '5'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'every six hours'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '13 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User entered empty.	System	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User entered empty.	System	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:55
User entered empty.	System	23 Apr 2021 15:49:54

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 15:57:08
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 15:57:08
Data point term sent to Coder	System	23 Apr 2021 15:51:51
User entered 'Ferrous sulfate'	(b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '325'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'twice daily (BID)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered 'Yes (Y)'	(b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 15:51:09

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: OTHER NERVOUS SYSTEM DRUGS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 15:57:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 15:57:56
Data point term sent to Coder	System	23 Apr 2021 15:53:02
User entered 'Gabapentin'	(b) (4), (b) (6) (b) (4)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered '800'	(b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 15:53:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	23 Apr 2021 15:53:07
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 15:53:07
User opened query 'Data is required. Please complete.' (Site from System).	System	23 Apr 2021 15:52:52
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:52:52

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
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: LORATADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 15:59:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 15:59:58
Data point term sent to Coder	System	23 Apr 2021 15:55:03
User entered 'Loratadine'	(b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '10'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 15:54:38

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:02:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:02:54
Data point term sent to Coder	System	23 Apr 2021 15:59:11
User entered 'methocarbamol'	(b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '750'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered 'every 6 hours'	(b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered 'I'	(b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:58:25

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: DOPAMINE AGONISTS, PRODUCT: ROPINIROLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:02:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:02:54
Data point term sent to Coder	System	23 Apr 2021 16:00:12
User entered 'ropinirole'	(b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0.25'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'unknown (UNKNOWN)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Apr 2021 15:59:30

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: DOCUSATE SODIUM;SENNOSIDE A+B, PRODUCTSYNONYM: DOCUSATE/SENNOSIDES - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Apr 2021 16:05:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:05:51
Data point term sent to Coder	System	23 Apr 2021 16:01:14
User entered 'Sennosideides-docusate'	(b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '8.6/50'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered 'twice daily (BID)'	(b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
	(b) (4)	
User entered empty.	(b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	23 Apr 2021 16:00:37

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OTHER GENERAL ANESTHETICS, PRODUCT: ANESTHETICS, GENERAL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:25:09
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:25:09
Data point term sent to Coder	System	23 Apr 2021 16:08:23
User entered 'General endotracheal anesthesia'	(b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'unknown'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'per hospital protocol'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User entered empty.	System	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User entered empty.	System	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:27
User entered empty.	System	23 Apr 2021 16:07:39

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:35:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:35:06
Data point term sent to Coder	System	23 Apr 2021 16:10:25
User entered 'Sodium chloride'	(b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '10'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'as needed (PRN)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '06 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User entered empty.	System	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User entered empty.	System	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:32
User entered empty.	System	23 Apr 2021 16:10:00

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:20:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:20:49
Data point term sent to Coder	System	23 Apr 2021 16:19:35
User entered 'Acetaminophen'	(b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '650'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'other (OTHER)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:31:55
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	23 Apr 2021 16:31:23
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	23 Apr 2021 16:31:23
User entered 'as needed (PRN)' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 16:31:23
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	23 Apr 2021 16:30:56
User entered 'once (ONCE)'	(b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Every 4 hours as needed' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Apr 2021 16:31:55
User entered empty.		23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '06 Feb 2021' reason for change: Data Entry Error	(b) (4)	23 Apr 2021 16:30:56
User entered '26 Jan 2021'	(b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User entered empty.	System	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User entered empty.	System	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:38
User entered empty.	System	23 Apr 2021 16:19:22

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:26:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:26:49
Data point term sent to Coder	System	23 Apr 2021 16:22:39
User entered 'Hydromorphone (Dilaudid)'	(b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0.5'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Intravenous Drip (INTRAVENOUS DRIP)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User entered empty.	System	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User entered empty.	System	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:31
User entered empty.	System	23 Apr 2021 16:22:04

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: VARIOUS, ATC: CONTRAST MEDIA, ATC: X-RAY CONTRAST MEDIA, IODINATED, ATC: WATERSOLUBLE, NEPHROTROPIC, LOW OSMOLAR X-RAY CONTRAST MEDIA, PRODUCT: IOVERSOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Apr 2021 12:26:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:26:51
Data point term sent to Coder	System	23 Apr 2021 16:24:41
User entered 'Ioversol'	(b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '75'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User entered empty.	System	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User entered empty.	System	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:47:44
User entered empty.	System	23 Apr 2021 16:24:24

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS AFFECTING THE ELECTROLYTE BALANCE, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:35:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:35:06
Data point term sent to Coder	System	23 Apr 2021 16:25:42
User entered 'Sodium Chloride'	(b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '1000'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Intravenous Bolus (INTRAVENOUS BOLUS)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User entered empty.	System	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User entered empty.	System	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:13
User entered empty.	System	23 Apr 2021 16:25:29

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: BETA-LACTAM ANTIBACTERIALS, PENICILLINS, ATC: COMBINATIONS OF PENICILLINS, INCL. BETA-LACTAMASE INHIBITORS, PRODUCT: PIPERACILLIN;TAZOBACTAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:29:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:29:55
Data point term sent to Coder	System	23 Apr 2021 16:26:58
User entered 'Piperacillin-tazobactam'	(b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '3.375'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User entered empty.	System	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User entered empty.	System	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:46:45
User entered empty.	System	23 Apr 2021 16:26:46

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:35:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:35:53
Data point term sent to Coder	System	23 Apr 2021 16:28:09
User entered 'Vancomycin'	(b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'I'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'g (g)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'once (ONCE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User entered empty.	System	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User entered empty.	System	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:49:24
User entered empty.	System	23 Apr 2021 16:27:35

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:35:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:35:53
Data point term sent to Coder	System	23 Apr 2021 16:30:11
User entered 'Vancomycin'	(b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '20'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mL (mL)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'every hour hour'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User entered empty.	System	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User entered empty.	System	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:20
User entered empty.	System	23 Apr 2021 16:29:16

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
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)	23 Apr 2021 16:36:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:36:55
Data point term sent to Coder	System	23 Apr 2021 16:35:14
User entered 'Heparin'	(b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '5000'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Every 8 hours'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '27 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User entered empty.	System	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User entered empty.	System	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:23
User entered empty.	System	23 Apr 2021 16:34:20

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	23 Apr 2021 16:42:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Apr 2021 16:42:52
Data point term sent to Coder	System	23 Apr 2021 16:36:15
User entered 'Ondansetron'	(b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '4'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'every 6 hours as needed'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Intravenous (INTRAVENOUS)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '02 Feb 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User entered empty.	System	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User entered empty.	System	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:47
User entered empty.	System	23 Apr 2021 16:36:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: INSULINS AND ANALOGUES, ATC: INSULINS AND ANALOGUES FOR INJECTION, FAST-ACTING, PRODUCT: INSULIN ASPART, PRODUCTSYNONYM: NOVOLOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	24 Apr 2021 12:33:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Apr 2021 12:33:50
Data point term sent to Coder	System	23 Apr 2021 16:39:19
User entered 'Novolog'	(b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'post op infection'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'UNK'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'IU (IU)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'other (OTHER)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Per sliding scale'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Subcutaneous (SUBCUTANEOUS)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '26 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '0'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User closed query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4)	26 Apr 2021 12:16:44
User entered '06 Feb 2021' reason for change: Data Entry Error	System	26 Apr 2021 12:16:44
User opened query 'End date is prior to start date. Please correct.' (Site from System).	(b) (4), (b) (6)	23 Apr 2021 16:39:03
User entered '06 Jan 2021'	(b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User entered empty.	System	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User entered empty.	System	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:29:16

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 02:48:53
User entered empty.	System	23 Apr 2021 16:39:03

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:29:16

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:51
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	09 Apr 2021 14:55:24
User entered 'No (N)'	Steven Anderson (b) (4)	07 Aug 2020 13:27:05

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:29:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:51
	(b) (4)	
User entered '05 Jan 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	09 Apr 2021 15:08:08
	(b) (4)	
User entered '03 Jan 2021'	Andrea Newlands (b) (4)	09 Apr 2021 14:56:09
	(b) (4)	

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:29:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:51
	(b) (4)	
User entered 'back surgery'	Andrea Newlands (b) (4)	09 Apr 2021 14:56:09
	(b) (4)	

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:51
	(b) (4)	
User entered 'Adverse Event (AE)'	Andrea Newlands (b) (4)	09 Apr 2021 14:56:09
	(b) (4)	

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:29:16

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:51
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 14:56:09
	(b) (4)	

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:29:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:46
DataPoint Verified.		20 Apr 2021 17:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:51
User entered '08 Jan 2021'	(b) (4) Andrea Newlands (b) (4)	09 Apr 2021 14:56:26
	(b) (4)	

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:29:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:46
DataPoint Verified.		20 Apr 2021 17:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:51
User entered 'back surgery'	(b) (4) Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 14:56:26

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:46
DataPoint Verified.		20 Apr 2021 17:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:51
User entered 'Adverse Event (AE)'	(b) (4)	
	Andrea Newlands (b) (4)	09 Apr 2021 14:56:26
	(b) (4)	

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:29:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:46
DataPoint Verified.		20 Apr 2021 17:12:26
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:31:51
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	09 Apr 2021 14:56:26
	(b) (4)	

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:29:16

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	23 Apr 2021 16:05:41
User entered '02 Feb 2021' reason for change: Data Entry Error	System	23 Apr 2021 16:05:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	23 Apr 2021 16:02:25
User entered 'UN Jan 2021' (non-conformant).	System	23 Apr 2021 16:02:25
	(b) (4), (b) (6)	23 Apr 2021 16:02:25

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:29:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Lumbar wound irrigation and debridement'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:25

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:25

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:29:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:48
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:02:25

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:29:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:50
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:48

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:29:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:50
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'MRI Lumbar spine w/o contrast'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:48

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:50
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:48

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:29:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:50
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:03:48

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:29:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '30 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:20

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:29:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'XR chest AP portable'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:20

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:20

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:29:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:20

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:29:16

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:57
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered '31 Jan 2021'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:57

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:29:16

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:57
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'CT Lumbar Spine without contrast'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:57

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:29:16

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:57
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:57

US3412067

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:29:16

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:40:57
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:39:26
User entered empty.	(b) (4) (b) (4), (b) (6)	23 Apr 2021 16:04:57

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'USA-US061-2021-MRNA-1273-P301000008'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Yes (Y)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Yes (Y)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered 'Richard'	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Gregory'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered 'Powell'	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Gottschlich'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered '4260 Glendale Milford Road'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Cincinnati'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'OH'	(b) (4) System	12 Apr 2021 13:56:14

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered '45242'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 20:26:39
User entered 'US'	System	08 Feb 2021 16:02:19

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Apr 2021 13:56:14
User entered '2'	System	18 Feb 2021 20:26:55
User entered '1'	System	08 Feb 2021 16:02:19

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'USA-US061-2021-MRNA-1273-P301000008'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Yes (Y)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Yes (Y)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered 'Richard'	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Gregory'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered 'Powell'	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Gottschlich'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered '4260 Glendale Milford Road'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Cincinnati'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'OH'	(b) (4) System	12 Apr 2021 13:56:14

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered '45242'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 20:26:39
User entered 'US'	System	08 Feb 2021 16:02:19

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Apr 2021 13:56:14
User entered '2'	System	18 Feb 2021 20:26:55
User entered '1'	System	08 Feb 2021 16:02:19

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:29:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '08/Feb/2021 11:02'	(b) (4) System	08 Feb 2021 16:02:19

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:29:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4), (b) (6)	18 Feb 2021 20:26:39
User entered 'I'		08 Feb 2021 16:02:19

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'USA-US061-2021-MRNA-1273-P301000008'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Yes (Y)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Yes (Y)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered 'Richard'	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Gregory'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered 'Powell'	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Gottschlich'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered '4260 Glendale Milford Road'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Cincinnati'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'OH'	(b) (4) System	12 Apr 2021 13:56:14

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered '45242'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 20:26:39
User entered 'US'	System	08 Feb 2021 16:02:19

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Apr 2021 13:56:14
User entered '2'	System	18 Feb 2021 20:26:55
User entered '1'	System	08 Feb 2021 16:02:19

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:29:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '18/Feb/2021 15:26'	(b) (4) System	18 Feb 2021 20:26:55

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:29:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4)	
	(b) (4), (b) (6)	18 Feb 2021 20:32:05
User entered 'I'	(b) (4), (b) (6)	18 Feb 2021 20:26:55

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'USA-US061-2021-MRNA-1273-P301000008'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Yes (Y)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Yes (Y)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'No (N)'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered 'Richard'	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Gregory'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered 'Powell'	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Gottschlich'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered '4260 Glendale Milford Road'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered 'Cincinnati'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'OH'	(b) (4) System	12 Apr 2021 13:56:14

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
	(b) (4)	
Un-reviewed for Safety.	System	12 Apr 2021 13:56:14
User entered empty.	System	12 Apr 2021 13:56:14
Reviewed for Safety.	(b) (4), (b) (6)	08 Feb 2021 16:00:25
User entered '45242'	System	08 Feb 2021 15:59:47

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	18 Feb 2021 20:26:39
User entered 'US'	System	08 Feb 2021 16:02:19

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form

Generated On: 09 Jun 2021 17:29:16

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '3'	System	12 Apr 2021 13:56:14
User entered '2'	System	18 Feb 2021 20:26:55
User entered '1'	System	08 Feb 2021 16:02:19

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:29:16

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered '12/Apr/2021 13:56'	(b) (4) System	12 Apr 2021 13:56:14

US3412067

Folder: SAE USA-US061-2021-MRNA-1273-P301000008

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:29:16

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:09:27
User entered 'I'	(b) (4) (b) (4), (b) (6)	12 Apr 2021 13:56:14