

US3412016 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:26:23

All time stamps listed in this document are displayed in GMT

US3412016

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Participant ID

US3412016

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

US3412016

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

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

Visit date (dd MMM yyyy)	29 JUL 2020
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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	SCRN
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US3412016

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
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

US3412016

Folder: Screening

Form: Enrollment

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Date of Informed Consent (*dd MMM yyyy*) 29 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

US3412016

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3412016

Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Were any significant conditions reported?

Yes ☒

No ☐

US3412016

Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

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)	_____

US3412016

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

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)	_____

US3412016

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

Condition	CAD
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)	_____

US3412016

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

Condition	DIABETES TYPE 2
Start date (dd MMM yyyy)	UN UNK 2008
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 2008
Start Year (derived)	2008
Stop Month and Year (derived)	
Stop Year (derived)	

US3412016

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

Condition	DIABETIC NEUROPATHY
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)	

US3412016

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

Condition	HEART ATTACK - MYOCARDIAL INFARCTION
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

US3412016

Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

Condition	HEART ATTACK - MYOCARDIAL INFARCTION
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2000
Start Year (derived)	2000
Stop Month and Year (derived)	JAN 2000
Stop Year (derived)	2000

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

Condition	BACK PAIN
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)	_____

US3412016

Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

Condition	STENT PLACEMENT X4
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: Medical History (11)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

Condition	ROTATOR CUFF REPAIR
Start date (dd MMM yyyy)	UN UNK 2019
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 2019
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2019
Start Year (derived)	2019
Stop Month and Year (derived)	JAN 2019
Stop Year (derived)	2019

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	29 JUL 2020
Time of assessment (00:00-23:59)	12:48 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 12:48
Height (xxx.x)	168.5 cm
Weight (xxx.x)	82.9 kg
BMI (xxx.x)	29.19811 kg/m ²
BMI units	KG/M2
Temperature (xxx.x)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	ND - Not Done
Pulse units	BPM
Respiratory Rate (xxx)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

29 JUL 2020

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

US3412016

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

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

WIFE WORKS FOR (b) (6),
TRAVELS, AND SON WORKS
WAREHOUSE

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:21:24

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

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

Visit date (dd MMM yyyy)	29 JUL 2020
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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	VISIT1
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US3412016

Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

What was the date of randomization? (dd MMM yyyy) 29 JUL 2020

What was the participant's randomization number? 142257

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 ☒

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Height	ND - Not Done
Weight	ND - Not Done

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

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)	29 JUL 2020
Time of assessment (00:00-23:59)	12:48 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 12:48
Temperature (xxx.x)	36.2 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	118 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	80 mmHg
Diastolic Blood Pressure units	MMHG

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

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)	29 JUL 2020
Time of assessment (00:00-23:59)	14:10 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 14:10
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	76 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	66 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 00:40:55

Generated On: 09 Jun 2021 17:26:23

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.

US3412016

Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

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) 29 JUL 2020

What was the treatment time? (00:00-23:59) 13:25 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 13:25

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 00:40:55

Generated On: 09 Jun 2021 17:26:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

29 JUL 2020

Collection time (00:00-23:59)

13:07 (24 HR)

Collection date and time (derived)

29 JUL 2020 13:07

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Collection date (dd MMM yyyy)			29 JUL 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	13:10	29 JUL 2020 13:10
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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

97.2 °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 JUL 2020 14:18

PC Open Date & Time

29 JUL 2020 13:45

PC Close Date & Time

29 JUL 2020 16:15

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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 97.2 °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 JUL 2020 21:18
PC Open Date & Time	29 JUL 2020 17:10
PC Close Date & Time	30 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

30 JUL 2020 21:18

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

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

31 JUL 2020 22:47

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

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

97.2 °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

01 AUG 2020 21:58

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

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

02 AUG 2020 22:22

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 21:03

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

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

97.2 °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 21:13

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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

29 JUL 2020 14:18

PC Open Date & Time

29 JUL 2020 13:45

PC Close Date & Time

29 JUL 2020 16:15

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

Please select one response below

None ☒

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

29 JUL 2020 21:19

PC Open Date & Time

29 JUL 2020 17:10

PC Close Date & Time

30 JUL 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

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

30 JUL 2020 21:19

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

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

31 JUL 2020 22:48

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

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

01 AUG 2020 21:58

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

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

02 AUG 2020 22:22

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

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

03 AUG 2020 21:03

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

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

04 AUG 2020 21:13

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 14:19
PC Open Date & Time	29 JUL 2020 13:45
PC Close Date & Time	29 JUL 2020 16:15

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 21:19
PC Open Date & Time	29 JUL 2020 17:10
PC Close Date & Time	30 JUL 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

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 ☒

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 21:19
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

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)

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 22:48
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

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 ☒

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 21:59
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

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

60 of 2606

EAB) (1725)

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 22:22
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

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

62 of 2606

EAB) (1725)

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

64 of 2606

EAB) (1725)

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

Yes <input type="checkbox"/>	
PC Time stamp	04 AUG 2020 21:13
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3412016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

05 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412016

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

19 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412016

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

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

Visit date (dd MMM yyyy)	26 AUG 2020
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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	VISIT2
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US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

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)	26 AUG 2020
Time of assessment (00:00-23:59)	10:03 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 10:03
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)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	134 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

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)	26 AUG 2020
Time of assessment (00:00-23:59)	11:26 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:26
Temperature (xxx.x)	97.2 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	72 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	140 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	78 mmHg
Diastolic Blood Pressure units	MMHG

US3412016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

26 AUG 2020

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

US3412016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

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) 26 AUG 2020

What was the treatment time? (00:00-23:59) 10:55 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 10:55

Which arm was used to give treatment? Left Arm ☒ Right Arm ☐

What was the frequency of the study treatment dosing? ONCE

What was the route of administration for the study treatment? INTRAMUSCULAR

US3412016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

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

Collection date (dd MMM yyyy)	26 AUG 2020
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Collection time (00:00-23:59)	10:20 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	26 AUG 2020 10:20
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US3412016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Collection date (dd MMM yyyy)			26 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	10:25	26 AUG 2020 10:25
Nasopharyngeal Swab 2	No		

US3412016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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

97.2 °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 26 AUG 2020 11:30

PC Open Date & Time 26 AUG 2020 11:15

PC Close Date & Time 26 AUG 2020 13:45

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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 97.2 °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	26 AUG 2020 14:40
PC Open Date & Time	26 AUG 2020 14:40
PC Close Date & Time	27 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

96.2 °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

27 AUG 2020 12:08

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 21:08

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

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

97.2 °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 23:41

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

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.

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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

30 AUG 2020 19:14

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

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.

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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

01 SEP 2020 08:24

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

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.

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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

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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

26 AUG 2020 11:30

PC Open Date & Time

26 AUG 2020 11:15

PC Close Date & Time

26 AUG 2020 13:45

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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

26 AUG 2020 14:41

PC Open Date & Time

26 AUG 2020 14:40

PC Close Date & Time

27 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

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

27 AUG 2020 12:09

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

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

28 AUG 2020 21:06

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

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

29 AUG 2020 23:41

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

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

30 AUG 2020 19:13

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

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

01 SEP 2020 08:25

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

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

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 11:31
PC Open Date & Time	26 AUG 2020 11:15
PC Close Date & Time	26 AUG 2020 13:45

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 14:41
PC Open Date & Time	26 AUG 2020 14:40
PC Close Date & Time	27 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

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US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 12:09
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

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 ☒

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 21:06
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

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 ☒

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EAB) (1725)

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 23:42
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

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)

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US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 19:14
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

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)

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Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

Yes <input type="checkbox"/>	
PC Time stamp	01 SEP 2020 08:25
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 7

HEADACHE

None ☐

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☐

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

Yes ☐

PC Time stamp

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

02 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412016

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:21:24

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

9 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412016

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

16 SEP 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412016

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	23 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

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

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) _____

US3412016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

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.

US3412016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	23 SEP 2020
Collection time (00:00-23:59)	9:30 (24 HR)
Collection date and time (derived)	23 SEP 2020 9:30

US3412016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:55

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 64

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 SEP 2020 21:25:54

Patient Cloud Open Date & Time

28 SEP 2020 00:01

Patient Cloud Close Date & Time

02 OCT 2020 23:59

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

05 OCT 2020 18:10:12

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 78

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 OCT 2020 09:24:08

Patient Cloud Open Date & Time

12 OCT 2020 00:01

Patient Cloud Close Date & Time

16 OCT 2020 23:59

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

26 OCT 2020 13:52:27

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

03 NOV 2020 01:05:05

Patient Cloud Open Date & Time

02 NOV 2020 00:01

Patient Cloud Close Date & Time

06 NOV 2020 23:59

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 106

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

09 NOV 2020 21:19:59

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 113

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

16 NOV 2020 17:44:37

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 117

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

20 NOV 2020 10:00:30

Patient Cloud Open Date & Time

20 NOV 2020 00:01

Patient Cloud Close Date & Time

24 NOV 2020 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

28 NOV 2020 22:00:11

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

07 DEC 2020 04:43:24

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

12 DEC 2020 06:03:50

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

18 DEC 2020 17:12:21

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

25 DEC 2020 14:15:34

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

01 JAN 2021 15:43:33

Patient Cloud Open Date & Time

01 JAN 2021 00:01

Patient Cloud Close Date & Time

05 JAN 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 166

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

10 JAN 2021 12:02:27

Patient Cloud Open Date & Time

08 JAN 2021 00:01

Patient Cloud Close Date & Time

12 JAN 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

15 JAN 2021 13:39:48

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 180

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

22 JAN 2021 00:26:38

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 187

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

29 JAN 2021 11:11:32

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 194

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

05 FEB 2021 00:05:59

Patient Cloud Open Date & Time

05 FEB 2021 00:01

Patient Cloud Close Date & Time

09 FEB 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 201

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 FEB 2021 08:15:04

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

19 FEB 2021 08:20:20

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

27 FEB 2021 13:57:03

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

05 MAR 2021 05:33:00

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 229

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

12 MAR 2021 01:16:15

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 236

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

19 MAR 2021 07:39:03

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

26 MAR 2021 13:01:19

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

02 APR 2021 03:50:10

Patient Cloud Open Date & Time

02 APR 2021 00:01

Patient Cloud Close Date & Time

06 APR 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

09 APR 2021 00:52:51

Patient Cloud Open Date & Time

09 APR 2021 00:01

Patient Cloud Close Date & Time

13 APR 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

17 APR 2021 11:46:08

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

23 APR 2021 07:00:33

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 278

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

30 APR 2021 09:54:17

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 292

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

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

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

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

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

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

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

18 MAY 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 MAY 2021 00:01
Patient Cloud Close Date & Time	25 MAY 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

[Patient Cloud Open Date & Time](#)

28 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

01 JUN 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

15 JUN 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 327

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

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

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

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

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

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

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

25 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

29 JUN 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 341

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

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

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

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

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

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

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	02 JUL 2021 00:01
Patient Cloud Close Date & Time	06 JUL 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

16 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

20 JUL 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

27 JUL 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

03 AUG 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 376

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

13 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

17 AUG 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

24 AUG 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

27 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

31 AUG 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

[Patient Cloud Open Date & Time](#)

03 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

07 SEP 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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"/>

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

[Patient Cloud Open Date & Time](#)

10 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

14 SEP 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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°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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 <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"/>

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

05 OCT 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 OCT 2021 00:01
Patient Cloud Close Date & Time	12 OCT 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT	DAY 446
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

26 OCT 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 467

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

16 NOV 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 488

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

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

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

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

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

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

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

14 DEC 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

21 DEC 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

28 DEC 2021 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

31 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

04 JAN 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

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11 JAN 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

14 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

18 JAN 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

25 JAN 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

[Patient Cloud Open Date & Time](#)

28 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

01 FEB 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

11 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

15 FEB 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 572

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

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

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

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

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

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

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

18 FEB 2022 00:01

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22 FEB 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 579

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

[Patient Cloud Open Date & Time](#)

25 FEB 2022 00:01

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01 MAR 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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°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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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08 MAR 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 593

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

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11 MAR 2022 00:01

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15 MAR 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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"/>

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and 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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18 MAR 2022 00:01

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22 MAR 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

[Patient Cloud Open Date & Time](#)

25 MAR 2022 00:01

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29 MAR 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 614

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

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

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

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

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

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

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 APR 2022 00:01

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05 APR 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 621

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

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

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

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

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

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

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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12 APR 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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°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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 APR 2022 00:01

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19 APR 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

22 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

26 APR 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 649

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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Date and time of submission

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

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10 MAY 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

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Date and time of submission

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

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17 MAY 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

[Patient Cloud Open Date & Time](#)

27 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

31 MAY 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 684

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

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

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

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

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

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

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

10 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

14 JUN 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT	DAY 691
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 698

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

08 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

12 JUL 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

15 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

19 JUL 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

29 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

02 AUG 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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="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"/>

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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="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"/>

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

12 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

16 AUG 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 761

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

26 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

DAY 768

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

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

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

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

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

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

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

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

[Patient Cloud Close Date & Time](#)

13 SEP 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

[Patient Cloud Open Date & Time](#)

16 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

20 SEP 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

23 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

27 SEP 2022 23:59

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	30 SEP 2022 00:01
Patient Cloud Close Date & Time	04 OCT 2022 23:59

US3412016

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:26:23

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		01 MAR 2021 16:50:52

US3412016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 OCT 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412016

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:26:02

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

23 DEC 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412016

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412016

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

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

Visit date (dd MMM yyyy)	19 FEB 2021
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Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	VISIT4
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US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

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) _____

US3412016

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

19 FEB 2021

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

US3412016

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

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

Collection date (dd MMM yyyy)	19 FEB 2021
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Collection time (00:00-23:59)	11:06 (24 HR)
-------------------------------	---------------

Collection date and time (derived)	19 FEB 2021 11:06
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US3412016

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

22 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412016

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:38:14

Generated On: 09 Jun 2021 17:26:23

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

20 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412016

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:38:14

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412016

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412016

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:26:23

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"/>

US3412016

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:26:23

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412016

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

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

Visit date (dd MMM yyyy)	11 JAN 2021
--------------------------	-------------

Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>

Folder OID	UNBLND_DECIDE
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US3412016

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 13:52:00

Generated On: 09 Jun 2021 17:26:23

Date of updated informed consent (dd MMM yyyy) 11 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

Under what version of the Protocol was the Participant unblinded? Amendment 5 ☐ Amendment 6 or later ☒

Date of unblinding (dd MMM yyyy) 11 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

Actual Dose 1 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Actual Dose 2 mRNA-1273 ☒ Placebo ☐ Not Administered ☐

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3412016

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

11 JAN 2021

Collection time (00:00-23:59)

10:43 (24 HR)

Collection date and time (derived)

11 JAN 2021 10:43

US3412016

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	11 JAN 2021
Collection time (00:00 - 23:59)	10:46
Collection Date and Time (derived)	11 JAN 2021 10:46

US3412016

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:25:04

Generated On: 09 Jun 2021 17:26:23

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 16 Apr 2021 13:28:59

Generated On: 09 Jun 2021 17:26:23

AEID	
Adverse event	SOB
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)	15 DEC 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (3)

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

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 13:28:59

Generated On: 09 Jun 2021 17:26:23

AEID	
Adverse event	VOCAL CORD SWELLING
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)	4 DEC 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 checked="" type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input type="radio"/>
Is the adverse event serious?	Yes <input type="radio"/> No <input checked="" type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	False
Hospital Admission Date (dd MMM yyyy)	
Hospital Discharge Date (dd MMM yyyy)	
Admitted to ICU?	Yes <input type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	

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Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 16 Apr 2021 13:28:59

Generated On: 09 Jun 2021 17:26:23

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 13:28:59

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AEID	USA-US061-2020-MRNA-1273-P30 1000018
Adverse event	ACUTE CHEST PAIN
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	2 DEC 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input type="radio"/> No <input checked="" type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	4 DEC 2020
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	2 DEC 2020
Hospital Discharge Date (dd MMM yyyy)	4 DEC 2020
Admitted to ICU?	Yes <input type="radio"/> No <input checked="" type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 13:28:59

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

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Folder: Adverse Events

Form: Adverse Events (5)

Data signed: (b) (4) 16 Apr 2021 13:28:59

Generated On: 09 Jun 2021 17:26:23

PREVIOUS SAE
USA-US061-2020-MRNA-1273P30
1000018 OF MI IS BEING
REVISED DUE TO RECEIPT OF
THE SUBJECTS MEDICAL
RECORDS. MEDICAL RECORDS
STATE CHEST PAIN MID
SUBSTERNAL WITHOUT
RADIATION WOKE HIM FROM
HIS SLEEP @ 01:00 ON 12/2/2020.
SUBJECT WENT TO THE ER
DEPARTMENT, WAS
EVALUATED, A CARDIAC
CATH WAS PERFORMED AND
PLACEMENT OF 2 STENTS
WERE COMPLETED. SUBJECT
WAS DISCHARGED FROM THE
HOSPITAL ON 12/4/2020.

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 05 Apr 2021 14:58:12

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

Yes ☒

No ☐

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:29:00

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Name of Medication ASPIRIN

Prophylaxis Yes ☐
No ☒

Indication HEART ATTACK

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:29:00

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	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:29:00

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Name of Medication LIPITOR

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 80

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) 16 Apr 2021 13:29:00

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	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:29:00

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Name of Medication JARDIANCE

Prophylaxis Yes ☐
No ☒

Indication DM2

Dose per administration 25

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication FENOFIBRATE

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 145

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) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:29:00

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Name of Medication FLEXERIL

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

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 (5)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 13:29:00

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Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication DIABETIC NEUROPATHY

Dose per administration 400

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) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)	3	
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 (7)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication HUMALOG

Prophylaxis Yes ☐
No ☒

Indication DM2

Dose per administration 100

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

If dose unit is Other, specify UNITS/ML

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 13:29:00

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	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication ISOSORBIDE DINITRATE

Prophylaxis Yes ☐
No ☒

Indication HEART ATTACK

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 (8)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	3 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (9)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication LORATADINE

Prophylaxis Yes ☐
No ☒

Indication ALLERGIC - SEASONAL

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 (10)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication METFORMIN

Prophylaxis Yes ☐
No ☒

Indication DM2

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)	3	
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 (12)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication METOPROLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)	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) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication HEART ATTACK

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 (13)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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 (15)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication PRIMIDONE

Prophylaxis Yes ☐
No ☒

Indication ESSENTIAL TREMOR

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 (15)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input 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 (16)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication JANUVIA

Prophylaxis Yes ☐
No ☒

Indication DM2

Dose per administration 100

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) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	4 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication TRAMADOL

Prophylaxis Yes ☐
No ☒

Indication BACK PAIN

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 (17)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input 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 (18)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication ZETIA

Prophylaxis Yes ☐
No ☒

Indication HYPERLIPIDEMIA

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication INFLUENZA 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 (19)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)		30 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		30 SEP 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 13:29:00

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Name of Medication METOPROLOLTARTRATE

Prophylaxis Yes ☐
No ☒

Indication HTN

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 (20)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		09 DEC 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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication ZOLPIDEN

Prophylaxis Yes ☐
No ☒

Indication INSOMNIA

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 (21)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)		9 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication BAYER ASPIRIN

Prophylaxis Yes ☒
No ☐

Indication STROKE PREVENTION

Dose per administration 81

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)	9 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication SOB

Dose per administration 90

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	15 JAN 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 (24)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication VITAMIN D

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 1250

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

TWICE WEEKLY

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) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)		04 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication ISOSORBIDE DINITRATE

Prophylaxis Yes ☐
No ☒

Indication ACUTE CHEST 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 (25)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)		4 DEC 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 checked="" type="radio"/>
	No	<input type="radio"/>
Separate Dosage Number (derived)		3
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 (26)

Data signed: (b) (4) 16 Apr 2021 13:29:00

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Name of Medication NOVOLOG

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 100

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

If dose unit is Other, specify IU/ML

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)		04 DEC 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication OLOPATADINE 0.7%

Prophylaxis Yes ☐
No ☒

Indication SEASONAL ALLERGIES

Dose per administration 1

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

If dose unit is Other, specify DROP

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 (27)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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	OPHTHALMIC	
Start date (dd MMM yyyy)	UN MAR 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication RANOLAZINE

Prophylaxis Yes ☐
No ☒

Indication ACUTE CHEST PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)		04 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		2
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication FENTANYL

Prophylaxis Yes ☐
No ☒

Indication PCI

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 (29)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)		03 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication	VERSED
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PCI
Dose per administration	2
Dose unit	mg <input checked="" type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input type="radio"/>
If dose unit is Other, specify _____	
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify _____	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)	03 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="radio"/>	
	No <input checked="" type="radio"/>	
If not Ongoing, End date (dd MMM yyyy)	03 DEC 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"/>	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication VERSED

Prophylaxis Yes ☐

No ☒

Indication PCI

Dose per administration 1

Dose unit mg ☒

ug ☐

mL ☐

g ☐

IU ☐

tablet ☐

capsule ☐

puff ☐

Other ☐

If dose unit is Other, specify

Frequency once daily ☐

twice daily ☐

three times daily ☐

four times daily ☐

every other day ☐

every week ☐

every month ☐

as needed ☐

once ☒

unknown ☐

other ☐

If frequency is Other, specify

Route of administration Oral ☐

Topical ☐

Subcutaneous ☐

Transdermal ☐

Intraocular ☐

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)		03 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication LIDOCAINE 20MG/ML

Prophylaxis Yes ☐
No ☒

Indication PCI

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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	INJECTION	
Start date (dd MMM yyyy)	03 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	03 DEC 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"/>

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication VERAPAMIL

Prophylaxis Yes ☐
No ☒

Indication PCI

Dose per administration 2.5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)		03 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication	HEPARIN
Prophylaxis	Yes <input type="radio"/> No <input checked="" type="radio"/>
Indication	PCI
Dose per administration	2
Dose unit	mg <input type="radio"/> ug <input type="radio"/> mL <input type="radio"/> g <input type="radio"/> IU <input type="radio"/> tablet <input type="radio"/> capsule <input type="radio"/> puff <input type="radio"/> Other <input checked="" type="radio"/>
If dose unit is Other, specify	IU/ML
Frequency	once daily <input type="radio"/> twice daily <input type="radio"/> three times daily <input type="radio"/> four times daily <input type="radio"/> every other day <input type="radio"/> every week <input type="radio"/> every month <input type="radio"/> as needed <input type="radio"/> once <input checked="" type="radio"/> unknown <input type="radio"/> other <input type="radio"/>
If frequency is Other, specify	
Route of administration	Oral <input type="radio"/> Topical <input type="radio"/> Subcutaneous <input type="radio"/> Transdermal <input type="radio"/> Intraocular <input type="radio"/>

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)		03 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication NITROGLYCERIN

Prophylaxis Yes ☐
No ☒

Indication ACUTE CHEST PAIN

Dose per administration 200

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	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)		03 DEC 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

Name of Medication PLAVIX

Prophylaxis Yes ☒
No ☐

Indication THROMBOLIC EVENT
PREVENTION

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003

EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 16 Apr 2021 13:29:00

Generated On: 09 Jun 2021 17:26:23

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify		
Start date (dd MMM yyyy)	03 DEC 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		03 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 14:58:12

Generated On: 09 Jun 2021 17:26:23

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
9 DEC 2020	2 CORONARY ARTERY STENTS PLACED FOR MYOCARDIAL INFARCTION AE	Adverse Event	
03 FEB 2021	ECHOCARDIOGRAM	Adverse Event	
01 JAN 2021	NASOPHARYNGOSCOPY	Adverse Event	

US3412016

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:26:23

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

US3412016

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:26:23

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 ☐

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Data signed: (b) (4) 16 Apr 2021 13:52:00

Generated On: 09 Jun 2021 17:26:23

SAEID	USA-US061-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Data signed: (b) (4) 16 Apr 2021 13:52:00

Generated On: 09 Jun 2021 17:26:23

SAEID	USA-US061-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	15/DEC/2020 20:03
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

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Data signed: (b) (4) 16 Apr 2021 13:52:00

Generated On: 09 Jun 2021 17:26:23

SAEID	USA-US061-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	16/DEC/2020 14:16
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.	True

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Data signed: (b) (4) 16 Apr 2021 13:52:00

Generated On: 09 Jun 2021 17:26:23

SAEID	USA-US061-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	09/FEB/2021 12:30
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

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (4)

Data signed: (b) (4) 16 Apr 2021 13:52:00

Generated On: 09 Jun 2021 17:26:23

SAEID	USA-US061-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	22/FEB/2021 11:24
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

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (5)

Data signed: (b) (4) 16 Apr 2021 13:52:00

Generated On: 09 Jun 2021 17:26:23

SAEID	USA-US061-2020-MRNA-1273-P301000018
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	5
Date of submission (Pre-filled from custom function)	02/APR/2021 17:24
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

US3412016 (Prod: New Horizons Clinical Research)

US3412016

Form: Participant Creation

Generated On: 09 Jun 2021 17:26:23

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'US3412016'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:24:14

US3412016

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:22:44

US3412016

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:24:15

US3412016

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:22:44

US3412016

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'SCRN'	System	29 Jul 2020 17:22:44

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered (b) (6) 1962'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:24:16

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '58'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'YEARS'	System	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '58'	System	29 Jul 2020 17:25:13

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Male (M)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'I'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:26:23

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:24:38

US3412016

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:23

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:25:13

US3412016

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jul 2020'	System	29 Jul 2020 17:25:13

US3412016

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2020'	System	29 Jul 2020 17:25:13

US3412016

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:23

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Amendment 1 (1)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:25:13

US3412016

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:25:13

US3412016

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:25:13

US3412016

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:23

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:25:13

US3412016

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:23

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	29 Jul 2020 17:25:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Jul 2020 17:25:34
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	29 Jul 2020 17:25:34
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Jul 2020 17:25:13
User entered empty.	(b) (4), (b) (6)	29 Jul 2020 17:25:13

US3412016

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:23

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:24:15

US3412016

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:26:23

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'I'	System	29 Jul 2020 17:25:42

US3412016

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:25:42

US3412016

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:26:23

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:22:50

US3412016

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
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)	04 Aug 2020 20:26:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:26:04
Data point term sent to Coder	System	04 Aug 2020 20:25:34
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	04 Aug 2020 20:25:01

US3412016

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Un UNK 2010'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:01

US3412016

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:01

US3412016

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:01

US3412016

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:01

US3412016

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:01

US3412016

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2010'	System	04 Aug 2020 20:25:01

US3412016

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2010'	System	04 Aug 2020 20:25:01

US3412016

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:25:01

US3412016

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:25:01

US3412016

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
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)	04 Aug 2020 20:26:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:26:04
Data point term sent to Coder	System	04 Aug 2020 20:25:34
User entered 'Hypertension'	(b) (4), (b) (6)	04 Aug 2020 20:25:12

US3412016

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'UN UNK 2010'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:12

US3412016

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:12

US3412016

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:12

US3412016

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:12

US3412016

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:12

US3412016

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2010'	System	04 Aug 2020 20:25:12

US3412016

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2010'	System	04 Aug 2020 20:25:12

US3412016

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:25:12

US3412016

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:25:12

US3412016

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery disease, LLT: Coronary artery disease - version MedDRA\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	04 Aug 2020 22:40:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 22:40:02
Data point term sent to Coder	System	04 Aug 2020 20:25:35
User entered 'CAD'	(b) (4), (b) (6)	04 Aug 2020 20:25:24

US3412016

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Un UNK 2010'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:24

US3412016

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:24

US3412016

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:24

US3412016

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:24

US3412016

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:24

US3412016

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2010'	System	04 Aug 2020 20:25:24

US3412016

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2010'	System	04 Aug 2020 20:25:24

US3412016

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:25:24

US3412016

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:25:24

US3412016

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
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)	04 Aug 2020 20:28:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:28:08
Data point term sent to Coder	System	04 Aug 2020 20:26:36
User entered 'Diabetes Type 2'	(b) (4), (b) (6)	04 Aug 2020 20:25:36

US3412016

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'UN UNK 2008'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:36

US3412016

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:36

US3412016

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:36

US3412016

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:36

US3412016

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:25:36

US3412016

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2008'	System	04 Aug 2020 20:25:36

US3412016

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2008'	System	04 Aug 2020 20:25:36

US3412016

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:25:36

US3412016

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:25:36

US3412016

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User closed query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:43:37
Query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' answered with 'unknown ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:03:48
User opened query 'Per DM CLR: Please verify the type of the Neuropathy (i.e. sensory or motor) and location (arms, legs, etc.). Review and update medical history diagnosis as appropriate and ensure update to MHx is reconciled with any corresponding AE or ConMed entries, if applicable. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 06:37:16
User coded data point as SOC: Nervous system disorders, HLGT: Peripheral neuropathies, HLT: Chronic polyneuropathies, PT: Diabetic neuropathy, LLT: Diabetic neuropathy - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 20:28:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 20:28:08
Data point term sent to Coder	System	04 Aug 2020 20:26:36
User entered 'Diabetic Neuropathy'	(b) (4), (b) (6)	04 Aug 2020 20:26:02

US3412016

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Un UNK 2018'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:26:02

US3412016

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:26:02

US3412016

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:26:02

US3412016

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:26:02

US3412016

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:26:02

US3412016

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2018'	System	04 Aug 2020 20:26:02

US3412016

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2018'	System	04 Aug 2020 20:26:02

US3412016

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:26:02

US3412016

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:26:02

US3412016

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User closed query 'Per MM, please confirm the term or diagnosis' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:43:54
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:36:50
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:36:50
Query 'Per MM, please confirm the term or diagnosis' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:04:57
Data point term sent to Coder	System	29 Sep 2020 17:04:56
Coding entries removed.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:04:50
User entered 'HEART ATTACK - myocardial infarction' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:04:50
User opened query 'Per MM, please confirm the term or diagnosis' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:39:08
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Heart attack - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 20:28:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 20:28:08
Data point term sent to Coder	System	04 Aug 2020 20:26:38
User entered 'Heart Attack'	(b) (4), (b) (6)	04 Aug 2020 20:26:22

US3412016

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'UN UNK 2015'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:26:22

US3412016

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:26:22

US3412016

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	04 Aug 2020 20:30:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	04 Aug 2020 20:30:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Aug 2020 20:30:16
User opened query 'Data is required. Please complete.' (Site from System).	System	04 Aug 2020 20:26:22
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:26:22

US3412016

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'un UNK 2015' reason for change:	(b) (4), (b) (6)	04 Aug 2020 20:30:16
Data Entry Error		
User entered empty.		04 Aug 2020 20:26:22

US3412016

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:26:22

US3412016

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2015'	System	04 Aug 2020 20:26:22

US3412016

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2015'	System	04 Aug 2020 20:26:22

US3412016

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2015'	System	04 Aug 2020 20:30:16
User entered empty.	System	04 Aug 2020 20:26:22

US3412016

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2015'	System	04 Aug 2020 20:30:16
User entered empty.	System	04 Aug 2020 20:26:22

US3412016

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User closed query 'Per MM, please confirm the term or diagnosis' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:44:00
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:37:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Oct 2020 12:37:25
Data point term sent to Coder	System	29 Sep 2020 17:05:57
Query 'Per MM, please confirm the term or diagnosis' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:05:31
Coding entries removed.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:05:23
User entered 'HEART ATTACK - myocardial infarction' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:05:23
User opened query 'Per MM, please confirm the term or diagnosis' (Site from DM).	(b) (4), (b) (6)	28 Sep 2020 08:39:19
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Heart attack - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 20:28:09
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 20:28:09
Data point term sent to Coder	System	04 Aug 2020 20:27:38
User entered 'Heart Attack'	(b) (4), (b) (6)	04 Aug 2020 20:26:50

US3412016

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'UN UNK 2000'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:26:50

US3412016

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:26:50

US3412016

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Aug 2020 20:30:03
User entered 'Yes (Y)'		04 Aug 2020 20:26:50

US3412016

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'UN UNK 2000' reason for change: Data Entry Error	(b) (4), (b) (6)	04 Aug 2020 20:30:03
User entered empty.		04 Aug 2020 20:26:50

US3412016

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:26:50

US3412016

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2000'	System	04 Aug 2020 20:26:50

US3412016

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2000'	System	04 Aug 2020 20:26:50

US3412016

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2000'	System	04 Aug 2020 20:30:03
User entered empty.	System	04 Aug 2020 20:26:50

US3412016

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2000'	System	04 Aug 2020 20:30:03
User entered empty.	System	04 Aug 2020 20:26:50

US3412016

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Back pain - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:30:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	04 Aug 2020 20:30:14
Data point term sent to Coder	System	04 Aug 2020 20:29:39
User entered 'Back pain'	(b) (4), (b) (6)	04 Aug 2020 20:29:18

US3412016

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'UN UNK 2010' reason for change:	(b) (4)	20 Nov 2020 15:42:57
Data Entry Error	(b) (4)	
User entered 'UN UNK 2019'	(b) (4), (b) (6)	04 Aug 2020 20:29:18

US3412016

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:29:18

US3412016

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:29:18

US3412016

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:29:18

US3412016

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:29:18

US3412016

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2010'	System	20 Nov 2020 15:42:57
User entered 'Jan 2019'	System	04 Aug 2020 20:29:18

US3412016

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2010'	System	20 Nov 2020 15:42:57
User entered '2019'	System	04 Aug 2020 20:29:18

US3412016

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:29:18

US3412016

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	04 Aug 2020 20:29:18

US3412016

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User coded data point as SOC: Nervous system disorders, HLGT: Movement disorders (incl parkinsonism), HLT: Tremor (excl congenital), PT: Essential tremor, LLT: Essential tremor - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 20:52:41
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	29 Sep 2020 20:52:41
Data point term sent to Coder	System	29 Sep 2020 20:51:51
User entered 'ESSENTIAL TREMOR'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 20:51:14

US3412016

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'UN UNK 2019'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 20:51:14

US3412016

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 20:51:14

US3412016

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 20:51:14

US3412016

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 20:51:14

US3412016

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	Mylene Asmar-Rios (b) (4)	29 Sep 2020 20:51:14

US3412016

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2019'	System	29 Sep 2020 20:51:14

US3412016

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2019'	System	29 Sep 2020 20:51:14

US3412016

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	29 Sep 2020 20:51:14

US3412016

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	29 Sep 2020 20:51:14

US3412016

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Therapeutic procedures and supportive care NEC, HLT: Therapeutic procedures NEC, PT: Stent placement, LLT: Stent placement - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 05:50:37
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	06 Oct 2020 05:50:37
Data point term sent to Coder	System	05 Oct 2020 19:10:51
User entered 'stent placement x4'	Steven Anderson (b) (4)	05 Oct 2020 19:10:19

US3412016

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'un UNK 2015'	Steven Anderson (b) (4)	05 Oct 2020 19:10:19

US3412016

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	Steven Anderson (b) (4)	05 Oct 2020 19:10:19

US3412016

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	Steven Anderson (b) (4)	05 Oct 2020 19:10:19

US3412016

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'un UNK 2015'	Steven Anderson (b) (4)	05 Oct 2020 19:10:19

US3412016

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	Steven Anderson (b) (4)	05 Oct 2020 19:10:19

US3412016

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2015'	System	05 Oct 2020 19:10:19

US3412016

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2015'	System	05 Oct 2020 19:10:19

US3412016

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2015'	System	05 Oct 2020 19:10:19

US3412016

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2015'	System	05 Oct 2020 19:10:19

US3412016

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User coded data point as SOC: Surgical and medical procedures, HLGT: Bone and joint therapeutic procedures, HLT: Joint therapeutic procedures, PT: Rotator cuff repair, LLT: Rotator cuff repair - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 19:12:23
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	05 Oct 2020 19:12:23
Data point term sent to Coder	System	05 Oct 2020 19:11:53
User entered 'rotator cuff repair'	Steven Anderson (b) (4)	05 Oct 2020 19:10:52

US3412016

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'un UNK 2019'	Steven Anderson (b) (4)	05 Oct 2020 19:10:52

US3412016

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	Steven Anderson (b) (4)	05 Oct 2020 19:10:52

US3412016

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	Steven Anderson (b) (4)	05 Oct 2020 19:10:52

US3412016

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'un UNK 2019'	Steven Anderson (b) (4)	05 Oct 2020 19:10:52

US3412016

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	Steven Anderson (b) (4)	05 Oct 2020 19:10:52

US3412016

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2019'	System	05 Oct 2020 19:10:52

US3412016

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2019'	System	05 Oct 2020 19:10:52

US3412016

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2019'	System	05 Oct 2020 19:10:52

US3412016

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2019'	System	05 Oct 2020 19:10:52

US3412016

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:23

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User coded data point as SOC: Immune system disorders, HLGT: Allergic conditions, HLT: Atopic disorders, PT: Seasonal allergy, LLT: Seasonal allergy - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 16:36:01
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	20 Nov 2020 16:36:01
Data point term sent to Coder	System	20 Nov 2020 16:03:58
User entered 'Allergic Seasonal'	Mylene Asmar-Rios	20 Nov 2020 16:03:53
	(b) (4)	

US3412016

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'un UNK 2012'	Mylene Asmar-Rios (b) (4)	20 Nov 2020 16:03:53

US3412016

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	Mylene Asmar-Rios (b) (4)	20 Nov 2020 16:03:53

US3412016

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	20 Nov 2020 16:03:53

US3412016

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	Mylene Asmar-Rios (b) (4)	20 Nov 2020 16:03:53

US3412016

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	Mylene Asmar-Rios (b) (4)	20 Nov 2020 16:03:53

US3412016

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2012'	System	20 Nov 2020 16:03:53

US3412016

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2012'	System	20 Nov 2020 16:03:53

US3412016

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	20 Nov 2020 16:03:53

US3412016

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	20 Nov 2020 16:03:53

US3412016

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:26:23

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:02
User coded data point as SOC: Psychiatric disorders, HLT: Sleep disorders and disturbances, HLT: Disturbances in initiating and maintaining sleep, PT: Insomnia, LLT: Insomnia - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 14:17:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Feb 2021 14:17:58
Data point term sent to Coder	System	22 Feb 2021 14:16:38
User entered 'insomnia'	Andrea Newlands (b) (4)	22 Feb 2021 14:16:26

US3412016

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:02
User entered 'un UNK 2012'	Andrea Newlands (b) (4)	22 Feb 2021 14:16:26

US3412016

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:02
User entered '0'	Andrea Newlands (b) (4)	22 Feb 2021 14:16:26

US3412016

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:26:23

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:02
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	22 Feb 2021 14:16:26

US3412016

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:02
User entered empty.	Andrea Newlands (b) (4)	22 Feb 2021 14:16:26

US3412016

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:26:23

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:02
User entered '0'	Andrea Newlands (b) (4)	22 Feb 2021 14:16:26

US3412016

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'Jan 2012'	System	22 Feb 2021 14:16:26

US3412016

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '2012'	System	22 Feb 2021 14:16:26

US3412016

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	22 Feb 2021 14:16:26

US3412016

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered empty.	System	22 Feb 2021 14:16:26

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '12:48'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered '29 Jul 2020 12:48'	System	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '168.5' cm	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:51
DataPoint set to visible.	System	29 Jul 2020 17:25:42

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '82.9' kg	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:51
DataPoint set to visible.	System	29 Jul 2020 17:25:42

US3412016

Folder: Screening

Form: Vital Signs

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BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
Amendment Manager: User entered '29.19811'	System	16 Sep 2020 23:38:08
User entered '29.2'	System	04 Aug 2020 20:23:51
DataPoint set to visible.	System	29 Jul 2020 17:25:42

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'kg/m2'	System	04 Aug 2020 20:23:51
DataPoint set to visible.	System	29 Jul 2020 17:25:42

US3412016

Folder: Screening

Form: Vital Signs

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Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 15:35:50
User entered '36.2' C	(b) (4), (b) (6)	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User closed query 'Data is required. Please provide.' (Site from System).	(b) (4) (b) (4), (b) (6)	20 Aug 2020 04:23:47
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Mylene Asmar-Rios (b) (4)	19 Aug 2020 13:18:13
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 13:18:05
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 13:18:05
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

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[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 15:35:50
User entered '60'	(b) (4), (b) (6)	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'bpm'	System	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 15:35:50
User entered '15'	(b) (4), (b) (6)	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'breaths/min'	System	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 15:35:50
User entered '118'	(b) (4), (b) (6)	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

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[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'mmHg'	System	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	13 Aug 2020 15:35:50
User entered '80'	(b) (4), (b) (6)	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User entered 'mmHg'	System	04 Aug 2020 20:23:51

US3412016

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02

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Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02

US3412016

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:23:58

US3412016

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
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)	27 Aug 2020 13:35:41
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	26 Aug 2020 14:39:15
User entered '29 Jul 2020'	(b) (4), (b) (6)	04 Aug 2020 20:23:58

US3412016

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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Folder: Screening

Form: Risk of Exposure

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	14 Sep 2020 16:04:29
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'WIFE WORKS FOR (b) (6) , TRAVELS, AND SON WORKS WAREHOUSE'	(b) (4)	14 Sep 2020 16:04:29
reason for change: Data Entry Error	Mylene Asmar-Rios	
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 20:24:28

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:23

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

US3412016

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '1' reason for change: Data Entry Error	(b) (4)	14 Sep 2020 16:04:29
User entered '0'	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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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)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

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Folder: Screening

Form: Risk of Exposure

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:24:28

US3412016

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:23

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '0' reason for change: Data Entry Error	(b) (4)	14 Sep 2020 16:04:29
User entered '1'	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 20:24:28

US3412016

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:26:23

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:33:02
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty; reason for change Data Entry Error	(b) (4)	14 Sep 2020 16:04:29
User entered 'Lives in high risk county'	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 20:24:28

US3412016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:16:40

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Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:16:40

US3412016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[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 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:16:40

US3412016

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'VISIT1'	System	04 Aug 2020 20:16:40

US3412016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '29 JUL 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 17:19:33

US3412016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:23

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 01:15:11
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:15:11
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 17:19:33
User entered '142257' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 17:19:33

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Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '>=18 and <65 years and at risk (2)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 17:19:33

US3412016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:23

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 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:22:17

US3412016

Folder: Visit 1 Day 1

Form: Randomization

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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 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:22:17

US3412016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:22:17

US3412016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:23

[Diabetes \(Type I, Type 2, or gestational\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:22:17

US3412016

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:26:23

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:22:17

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:23

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User accepted default value 'Pre-Dose (PREDOSE)'		04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 15:38:24
User entered 'No (N)'	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '29 Jul 2020' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 15:38:24
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '12:48' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 15:38:24
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered '29 Jul 2020 12:48'	System	13 Aug 2020 15:38:24
User entered empty.	System	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '36.2' C reason for change: Data Entry Error	(b) (4)	13 Aug 2020 15:38:24
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 15:38:24
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '60' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 15:38:24
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'bpm'	System	13 Aug 2020 15:38:24
User entered empty.	System	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '16' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 15:38:24
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'breaths/min'	System	13 Aug 2020 15:38:24
User entered empty.	System	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '118' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 15:38:24
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'mmHg'	System	13 Aug 2020 15:38:24
User entered empty.	System	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '80' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 15:38:24
User entered empty.	Mylene Asmar-Rios (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'mmHg'	System	13 Aug 2020 15:38:24
User entered empty.	System	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:23

Height

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:26:23

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered missing code ND - Not Done.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User accepted default value 'Post-Dose (POSTDOSE)'		04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	17 Aug 2020 16:00:57
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, post dose vitals were taken 30 after injection' (Site from System).		11 Aug 2020 15:01:12
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).		04 Aug 2020 20:21:33
User entered '14:10'	(b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered '29 Jul 2020 14:10'	System	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '97.2' F	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Oral (Oral)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '76'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'bpm'	System	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '14'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'breaths/min'	System	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '124'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'mmHg'	System	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '66'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'mmHg'	System	04 Aug 2020 20:21:33

US3412016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:22:22

US3412016

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:23

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:22:22

US3412016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:27:20

US3412016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:27:20

US3412016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

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 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:27:20

US3412016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 17:27:20

US3412016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:27:20

US3412016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '13:25'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:27:20

US3412016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered '29 Jul 2020 13:25'	System	29 Jul 2020 17:27:20

US3412016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	29 Jul 2020 17:27:20

US3412016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

What was the frequency of the study treatment dosing?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'ONCE'	System	29 Jul 2020 17:27:20

US3412016

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 17:27:20

US3412016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:20:41

US3412016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:20:41

US3412016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '13:07'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:20:41

US3412016

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered '29 Jul 2020 13:07'	System	04 Aug 2020 20:20:41

US3412016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:26:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '29 Jul 2020'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:20:27

US3412016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		04 Aug 2020 20:20:27

US3412016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:20:27

US3412016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:23

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '13:10'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:20:27

US3412016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered '29 Jul 2020 13:10'	System	04 Aug 2020 20:20:27

US3412016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		04 Aug 2020 20:20:27

US3412016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:20:27

US3412016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:23

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:20:27

US3412016

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered empty.	System	04 Aug 2020 20:20:27

US3412016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 20:16:44

US3412016

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'I'	System	04 Aug 2020 20:16:44

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:17:16', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '16ce6dab-a16d-438a-96ea-05ce4614c1e1' User entered 'Yes (Y)'	System	29 Jul 2020 18:18:10
	System	29 Jul 2020 18:18:10

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:17:26', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '16ce6dab-a16d-438a-96ea-05ce4614c1e1' User entered '97.2'	System	29 Jul 2020 18:18:10
	System	29 Jul 2020 18:18:10

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:17:59', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '16ce6dab-a16d-438a-96ea-05ce4614c1e1' User entered 'No (N)'	System	29 Jul 2020 18:18:10
	System	29 Jul 2020 18:18:10

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:18:08', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '16ce6dab-a16d-438a-96ea-05ce4614c1e1' User entered '29 Jul 2020 14:18'	System	29 Jul 2020 18:18:10
	System	29 Jul 2020 18:18:10

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Jul 2020 13:45'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Jul 2020 16:15'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:18:23', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '9849fc8b-9aa6-4e65-8725-f5d8ca89669b' User entered 'Yes (Y)'	System	30 Jul 2020 01:20:09
	System	30 Jul 2020 01:20:09

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:18:31', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '9849fc8b-9aa6-4e65-8725-f5d8ca89669b' User entered '97.2'	System	30 Jul 2020 01:20:09
	System	30 Jul 2020 01:20:09

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:18:35', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '9849fc8b-9aa6-4e65-8725-f5d8ca89669b' User entered 'No (N)'	System	30 Jul 2020 01:20:09
	System	30 Jul 2020 01:20:09

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:18:43', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '9849fc8b-9aa6-4e65-8725-f5d8ca89669b' User entered '29 Jul 2020 21:18'	System	30 Jul 2020 01:20:09
	System	30 Jul 2020 01:20:09

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Jul 2020 17:10'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 2'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:18:14', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'd22a33b4-e1e5-4210-b9c6-858934a75bef'	System	06 Aug 2020 14:50:29
User entered 'Yes (Y)'	System	06 Aug 2020 14:50:29

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:18:21', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'd22a33b4-e1e5-4210-b9c6-858934a75bef' User entered '98.3'	System	06 Aug 2020 14:50:29
	System	06 Aug 2020 14:50:29

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:18:27', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'd22a33b4-e1e5-4210-b9c6-858934a75bef'	System	06 Aug 2020 14:50:29
User entered 'No (N)'	System	06 Aug 2020 14:50:29

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:18:31', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'd22a33b4-e1e5-4210-b9c6-858934a75bef' User entered '30 Jul 2020 21:18'	System	06 Aug 2020 14:50:29
	System	06 Aug 2020 14:50:29

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 3'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:47:32', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '737492c5-00ce-4246-a47d-a4987d9ce737' User entered 'Yes (Y)'	System	06 Aug 2020 14:50:33
	System	06 Aug 2020 14:50:33

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:47:38', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '737492c5-00ce-4246-a47d-a4987d9ce737' User entered '97.2'	System	06 Aug 2020 14:50:33
	System	06 Aug 2020 14:50:33

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:47:43', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '737492c5-00ce-4246-a47d-a4987d9ce737'	System	06 Aug 2020 14:50:33
User entered 'No (N)'	System	06 Aug 2020 14:50:33

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:47:47', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '737492c5-00ce-4246-a47d-a4987d9ce737'	System	06 Aug 2020 14:50:33
User entered '31 Jul 2020 22:47'	System	06 Aug 2020 14:50:33

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 4'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:58:23', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '8809e358-f2b4-4b52-b464-73f85974fb06'	System	06 Aug 2020 14:50:34
User entered 'Yes (Y)'	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:58:29', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '8809e358-f2b4-4b52-b464-73f85974fb06'	System	06 Aug 2020 14:50:34
User entered '97.2'	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:58:33', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '8809e358-f2b4-4b52-b464-73f85974fb06'	System	06 Aug 2020 14:50:34
User entered 'No (N)'	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:58:36', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '8809e358-f2b4-4b52-b464-73f85974fb06'	System	06 Aug 2020 14:50:34
User entered '01 Aug 2020 21:58'	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 5'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:21:54', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f6c345ea-8850-45ca-b707-5a36ca90d795'	System	06 Aug 2020 14:50:35
User entered 'Yes (Y)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:03', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f6c345ea-8850-45ca-b707-5a36ca90d795' User entered '97.2'	System	06 Aug 2020 14:50:35
	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:06', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f6c345ea-8850-45ca-b707-5a36ca90d795'	System	06 Aug 2020 14:50:35
User entered 'No (N)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:09', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f6c345ea-8850-45ca-b707-5a36ca90d795'	System	06 Aug 2020 14:50:35
User entered '02 Aug 2020 22:22'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 6'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:03:29', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f9ba738d-6dd5-40e8-bf70-e91c3e34e774' User entered 'Yes (Y)'	System	06 Aug 2020 14:50:38
	System	06 Aug 2020 14:50:38

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:03:34', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f9ba738d-6dd5-40e8-bf70-e91c3e34e774' User entered '97.2'	System	06 Aug 2020 14:50:38
	System	06 Aug 2020 14:50:38

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:03:39', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f9ba738d-6dd5-40e8-bf70-e91c3e34e774'	System	06 Aug 2020 14:50:38
User entered 'No (N)'	System	06 Aug 2020 14:50:38

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:03:42', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f9ba738d-6dd5-40e8-bf70-e91c3e34e774' User entered '03 Aug 2020 21:03'	System	06 Aug 2020 14:50:38
	System	06 Aug 2020 14:50:38

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 7'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:09', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '66494c73-db0f-4537-8165-25b0e1c3e7b9' User entered 'Yes (Y)'	System	06 Aug 2020 14:50:39
	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:13', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '66494c73-db0f-4537-8165-25b0e1c3e7b9' User entered '97.2'	System	06 Aug 2020 14:50:39
	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:17', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '66494c73-db0f-4537-8165-25b0e1c3e7b9' User entered 'No (N)'	System	06 Aug 2020 14:50:39
	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:20', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '66494c73-db0f-4537-8165-25b0e1c3e7b9' User entered '04 Aug 2020 21:13'	System	06 Aug 2020 14:50:39
	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:18:21', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ea82ba22-1be3-4d77-87d4-46b39edde76b' User entered 'None (1)'	System	29 Jul 2020 18:18:46
	System	29 Jul 2020 18:18:46

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:18:26', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ea82ba22-1be3-4d77-87d4-46b39edde76b' User entered 'No (N)'	System	29 Jul 2020 18:18:46
	System	29 Jul 2020 18:18:46

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:18:30', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ea82ba22-1be3-4d77-87d4-46b39edde76b' User entered 'No (N)'	System	29 Jul 2020 18:18:46
	System	29 Jul 2020 18:18:46

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:18:36', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ea82ba22-1be3-4d77-87d4-46b39edde76b' User entered 'None (1)'	System	29 Jul 2020 18:18:46
	System	29 Jul 2020 18:18:46

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:18:40', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ea82ba22-1be3-4d77-87d4-46b39edde76b' User entered '29 Jul 2020 14:18'	System	29 Jul 2020 18:18:46
	System	29 Jul 2020 18:18:46

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Jul 2020 13:45'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Jul 2020 16:15'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:18:49', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '188ca5e7-8dfb-42ea-add1-9a3047610dc7' User entered 'None (1)'	System	30 Jul 2020 01:20:09
	System	30 Jul 2020 01:20:09

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:18:52', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '188ca5e7-8dfb-42ea-add1-9a3047610dc7' User entered 'No (N)'	System	30 Jul 2020 01:20:09
	System	30 Jul 2020 01:20:09

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:18:58', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '188ca5e7-8dfb-42ea-add1-9a3047610dc7' User entered 'No (N)'	System	30 Jul 2020 01:20:09
	System	30 Jul 2020 01:20:09

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:19:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '188ca5e7-8dfb-42ea-add1-9a3047610dc7' User entered 'None (1)'	System	30 Jul 2020 01:20:09
	System	30 Jul 2020 01:20:09

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:19:03', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '188ca5e7-8dfb-42ea-add1-9a3047610dc7' User entered '29 Jul 2020 21:19'	System	30 Jul 2020 01:20:09
	System	30 Jul 2020 01:20:09

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Jul 2020 17:10'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 2'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:18:41', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c006ffca-591a-4536-9eb3-d7a454839c20'	System	06 Aug 2020 14:50:31
User entered 'None (1)'	System	06 Aug 2020 14:50:31

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:18:45', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c006ffca-591a-4536-9eb3-d7a454839c20'	System	06 Aug 2020 14:50:31
User entered 'No (N)'	System	06 Aug 2020 14:50:31

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:18:50', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c006ffca-591a-4536-9eb3-d7a454839c20' User entered 'No (N)'	System	06 Aug 2020 14:50:31
	System	06 Aug 2020 14:50:31

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:18:54', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c006ffca-591a-4536-9eb3-d7a454839c20'	System	06 Aug 2020 14:50:31
User entered 'None (1)'	System	06 Aug 2020 14:50:31

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:19:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c006ffca-591a-4536-9eb3-d7a454839c20' User entered '30 Jul 2020 21:19'	System	06 Aug 2020 14:50:31
	System	06 Aug 2020 14:50:31

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 3'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:47:52', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f39d8e68-fdc2-4fdf-8b0b-b8c727b0f105'	System	06 Aug 2020 14:50:33
User entered 'None (1)'	System	06 Aug 2020 14:50:33

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:47:54', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f39d8e68-fdc2-4fdf-8b0b-b8c727b0f105'	System	06 Aug 2020 14:50:33
User entered 'No (N)'	System	06 Aug 2020 14:50:33

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:47:56', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f39d8e68-fdc2-4fdf-8b0b-b8c727b0f105'	System	06 Aug 2020 14:50:33
User entered 'No (N)'	System	06 Aug 2020 14:50:33

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:47:59', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f39d8e68-fdc2-4fdf-8b0b-b8c727b0f105'	System	06 Aug 2020 14:50:33
User entered 'None (1)'	System	06 Aug 2020 14:50:33

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:48:02', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f39d8e68-fdc2-4fdf-8b0b-b8c727b0f105'	System	06 Aug 2020 14:50:33
User entered '31 Jul 2020 22:48'	System	06 Aug 2020 14:50:33

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 4'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:58:41', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '759ca6ec-bbfe-49d5-b28b-7abc6827fe50'	System	06 Aug 2020 14:50:35
User entered 'None (1)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:58:45', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '759ca6ec-bbfe-49d5-b28b-7abc6827fe50'	System	06 Aug 2020 14:50:35
User entered 'No (N)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:58:47', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '759ca6ec-bbfe-49d5-b28b-7abc6827fe50'	System	06 Aug 2020 14:50:35
User entered 'No (N)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:58:49', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '759ca6ec-bbfe-49d5-b28b-7abc6827fe50'	System	06 Aug 2020 14:50:35
User entered 'None (1)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:58:52', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '759ca6ec-bbfe-49d5-b28b-7abc6827fe50'	System	06 Aug 2020 14:50:35
User entered '01 Aug 2020 21:58'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 5'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:15', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6601e97d-423a-41b8-93d1-28e0a91f849a' User entered 'None (1)'	System	06 Aug 2020 14:50:35
	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:18', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6601e97d-423a-41b8-93d1-28e0a91f849a' User entered 'No (N)'	System	06 Aug 2020 14:50:35
	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:20', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6601e97d-423a-41b8-93d1-28e0a91f849a' User entered 'No (N)'	System	06 Aug 2020 14:50:35
	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:22', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6601e97d-423a-41b8-93d1-28e0a91f849a' User entered 'None (1)'	System	06 Aug 2020 14:50:35
	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:25', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6601e97d-423a-41b8-93d1-28e0a91f849a' User entered '02 Aug 2020 22:22'	System	06 Aug 2020 14:50:35
	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 6'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:03:47', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7015cf25-7c62-466b-a4e2-9ebbb873830f' User entered 'None (1)'	System	06 Aug 2020 14:50:38
	System	06 Aug 2020 14:50:38

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:03:50', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7015cf25-7c62-466b-a4e2-9ebbb873830f' User entered 'No (N)'	System	06 Aug 2020 14:50:38
	System	06 Aug 2020 14:50:38

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:03:53', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7015cf25-7c62-466b-a4e2-9ebbb873830f' User entered 'No (N)'	System	06 Aug 2020 14:50:38
	System	06 Aug 2020 14:50:38

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:03:56', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7015cf25-7c62-466b-a4e2-9ebbb873830f' User entered 'None (1)'	System	06 Aug 2020 14:50:38
	System	06 Aug 2020 14:50:38

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:03:58', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7015cf25-7c62-466b-a4e2-9ebbb873830f' User entered '03 Aug 2020 21:03'	System	06 Aug 2020 14:50:38
	System	06 Aug 2020 14:50:38

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 7'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:25', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bcab6583-ec6d-4066-b3fd-979a942a3f65'	System	06 Aug 2020 14:50:40
User entered 'None (1)'	System	06 Aug 2020 14:50:40

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:29', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bcab6583-ec6d-4066-b3fd-979a942a3f65'	System	06 Aug 2020 14:50:40
User entered 'No (N)'	System	06 Aug 2020 14:50:40

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:31', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bcab6583-ec6d-4066-b3fd-979a942a3f65'	System	06 Aug 2020 14:50:40
User entered 'No (N)'	System	06 Aug 2020 14:50:40

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:33', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bcab6583-ec6d-4066-b3fd-979a942a3f65'	System	06 Aug 2020 14:50:40
User entered 'None (1)'	System	06 Aug 2020 14:50:40

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:35', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bcab6583-ec6d-4066-b3fd-979a942a3f65'	System	06 Aug 2020 14:50:40
User entered '04 Aug 2020 21:13'	System	06 Aug 2020 14:50:40

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:18:58', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6e4cfece-e513-4062-ba30-06636572a3a0' User entered 'None (0)'	System	29 Jul 2020 18:19:41
	System	29 Jul 2020 18:19:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:19:01', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6e4cfece-e513-4062-ba30-06636572a3a0' User entered 'None (0)'	System	29 Jul 2020 18:19:41
	System	29 Jul 2020 18:19:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:19:05', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6e4cfece-e513-4062-ba30-06636572a3a0' User entered 'None (0)'	System	29 Jul 2020 18:19:41
	System	29 Jul 2020 18:19:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:19:10', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6e4cfece-e513-4062-ba30-06636572a3a0' User entered 'None (0)'	System	29 Jul 2020 18:19:41
	System	29 Jul 2020 18:19:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:19:14', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6e4cfece-e513-4062-ba30-06636572a3a0' User entered 'None (0)'	System	29 Jul 2020 18:19:41
	System	29 Jul 2020 18:19:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:19:17', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6e4cfece-e513-4062-ba30-06636572a3a0' User entered 'None (0)'	System	29 Jul 2020 18:19:41
	System	29 Jul 2020 18:19:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:19:35', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6e4cfece-e513-4062-ba30-06636572a3a0' User entered 'No (N)'	System	29 Jul 2020 18:19:41
	System	29 Jul 2020 18:19:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T14:19:38', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6e4cfece-e513-4062-ba30-06636572a3a0' User entered '29 Jul 2020 14:19'	System	29 Jul 2020 18:19:41
	System	29 Jul 2020 18:19:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Jul 2020 13:45'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Jul 2020 16:15'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:19:08', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '67717f57-568c-49ad-8090-3febd343fed6' User entered 'None (0)'	System	30 Jul 2020 01:20:10
	System	30 Jul 2020 01:20:10

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:19:10', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '67717f57-568c-49ad-8090-3febd343fed6' User entered 'None (0)'	System	30 Jul 2020 01:20:10
	System	30 Jul 2020 01:20:10

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:19:13', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '67717f57-568c-49ad-8090-3febd343fed6' User entered 'None (0)'	System	30 Jul 2020 01:20:10
	System	30 Jul 2020 01:20:10

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:19:17', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '67717f57-568c-49ad-8090-3febd343fed6' User entered 'None (0)'	System	30 Jul 2020 01:20:10
	System	30 Jul 2020 01:20:10

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:19:20', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '67717f57-568c-49ad-8090-3febd343fed6' User entered 'None (0)'	System	30 Jul 2020 01:20:10
	System	30 Jul 2020 01:20:10

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:19:22', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '67717f57-568c-49ad-8090-3febd343fed6' User entered 'None (0)'	System	30 Jul 2020 01:20:10
	System	30 Jul 2020 01:20:10

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:19:27', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '67717f57-568c-49ad-8090-3febd343fed6'	System	30 Jul 2020 01:20:10
User entered 'No (N)'	System	30 Jul 2020 01:20:10

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-29T21:19:30', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '67717f57-568c-49ad-8090-3febd343fed6' User entered '29 Jul 2020 21:19'	System	30 Jul 2020 01:20:10
	System	30 Jul 2020 01:20:10

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Jul 2020 17:10'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 2'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:19:08', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fd119dc3-683c-42f3-8fb7-f93d683de747'	System	06 Aug 2020 14:50:32
User entered 'None (0)'	System	06 Aug 2020 14:50:32

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:19:11', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fd119dc3-683c-42f3-8fb7-f93d683de747'	System	06 Aug 2020 14:50:32
User entered 'None (0)'	System	06 Aug 2020 14:50:32

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:19:16', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fd119dc3-683c-42f3-8fb7-f93d683de747'	System	06 Aug 2020 14:50:32
User entered 'None (0)'	System	06 Aug 2020 14:50:32

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:19:21', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fd119dc3-683c-42f3-8fb7-f93d683de747'	System	06 Aug 2020 14:50:32
User entered 'None (0)'	System	06 Aug 2020 14:50:32

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:19:23', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fd119dc3-683c-42f3-8fb7-f93d683de747'	System	06 Aug 2020 14:50:32
User entered 'None (0)'	System	06 Aug 2020 14:50:32

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:19:26', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fd119dc3-683c-42f3-8fb7-f93d683de747'	System	06 Aug 2020 14:50:32
User entered 'None (0)'	System	06 Aug 2020 14:50:32

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:19:31', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fd119dc3-683c-42f3-8fb7-f93d683de747'	System	06 Aug 2020 14:50:32
User entered 'No (N)'	System	06 Aug 2020 14:50:32

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-30T21:19:34', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fd119dc3-683c-42f3-8fb7-f93d683de747'	System	06 Aug 2020 14:50:32
User entered '30 Jul 2020 21:19'	System	06 Aug 2020 14:50:32

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 3'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:48:06', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '20c8350b-71cc-490d-bebf-b3f3da1e036f' User entered 'None (0)'	System	06 Aug 2020 14:50:34
	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:48:10', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '20c8350b-71cc-490d-bebf-b3f3da1e036f' User entered 'None (0)'	System	06 Aug 2020 14:50:34
	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:48:15', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '20c8350b-71cc-490d-bebf-b3f3da1e036f'	System	06 Aug 2020 14:50:34
User entered 'None (0)'	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:48:19', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '20c8350b-71cc-490d-bebf-b3f3da1e036f' User entered 'None (0)'	System	06 Aug 2020 14:50:34
	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:48:23', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '20c8350b-71cc-490d-bebf-b3f3da1e036f'	System	06 Aug 2020 14:50:34
User entered 'None (0)'	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:48:26', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '20c8350b-71cc-490d-bebf-b3f3da1e036f' User entered 'None (0)'	System	06 Aug 2020 14:50:34
	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:48:29', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '20c8350b-71cc-490d-bebf-b3f3da1e036f'	System	06 Aug 2020 14:50:34
User entered 'No (N)'	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-07-31T22:48:32', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '20c8350b-71cc-490d-bebf-b3f3da1e036f' User entered '31 Jul 2020 22:48'	System	06 Aug 2020 14:50:34
	System	06 Aug 2020 14:50:34

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 4'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:58:56', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '799514f0-cd01-4021-a668-7ebb846cfbf4'	System	06 Aug 2020 14:50:35
User entered 'None (0)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:58:58', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '799514f0-cd01-4021-a668-7ebb846cfbf4' User entered 'None (0)'	System	06 Aug 2020 14:50:35
	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:59:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '799514f0-cd01-4021-a668-7ebb846cfbf4'	System	06 Aug 2020 14:50:35
User entered 'None (0)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:59:02', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '799514f0-cd01-4021-a668-7ebb846cfbf4'	System	06 Aug 2020 14:50:35
User entered 'None (0)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:59:04', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '799514f0-cd01-4021-a668-7ebb846cfbf4'	System	06 Aug 2020 14:50:35
User entered 'None (0)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:59:06', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '799514f0-cd01-4021-a668-7ebb846cfbf4'	System	06 Aug 2020 14:50:35
User entered 'None (0)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:59:08', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '799514f0-cd01-4021-a668-7ebb846cfbf4'	System	06 Aug 2020 14:50:35
User entered 'No (N)'	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-01T21:59:11', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '799514f0-cd01-4021-a668-7ebb846cfbf4' User entered '01 Aug 2020 21:59'	System	06 Aug 2020 14:50:35
	System	06 Aug 2020 14:50:35

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 5'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:29', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '5b023889-9440-410b-817e-e10761888b69'	System	06 Aug 2020 14:50:37
User entered 'None (0)'	System	06 Aug 2020 14:50:37

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:31', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '5b023889-9440-410b-817e-e10761888b69'	System	06 Aug 2020 14:50:37
User entered 'None (0)'	System	06 Aug 2020 14:50:37

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:32', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '5b023889-9440-410b-817e-e10761888b69'	System	06 Aug 2020 14:50:37
User entered 'None (0)'	System	06 Aug 2020 14:50:37

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:35', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '5b023889-9440-410b-817e-e10761888b69'	System	06 Aug 2020 14:50:37
User entered 'None (0)'	System	06 Aug 2020 14:50:37

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:37', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '5b023889-9440-410b-817e-e10761888b69'	System	06 Aug 2020 14:50:37
User entered 'None (0)'	System	06 Aug 2020 14:50:37

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:39', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '5b023889-9440-410b-817e-e10761888b69'	System	06 Aug 2020 14:50:37
User entered 'None (0)'	System	06 Aug 2020 14:50:37

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:41', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '5b023889-9440-410b-817e-e10761888b69'	System	06 Aug 2020 14:50:37
User entered 'No (N)'	System	06 Aug 2020 14:50:37

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-02T22:22:44', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '5b023889-9440-410b-817e-e10761888b69'	System	06 Aug 2020 14:50:37
User entered '02 Aug 2020 22:22'	System	06 Aug 2020 14:50:37

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 6'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:04:03', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bf822240-14d7-4e22-942a-976218b33cbf'	System	06 Aug 2020 14:50:39
User entered 'None (0)'	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:04:06', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bf822240-14d7-4e22-942a-976218b33cbf' User entered 'None (0)'	System	06 Aug 2020 14:50:39
	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:04:08', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bf822240-14d7-4e22-942a-976218b33cbf'	System	06 Aug 2020 14:50:39
User entered 'None (0)'	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:04:11', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bf822240-14d7-4e22-942a-976218b33cbf'	System	06 Aug 2020 14:50:39
User entered 'None (0)'	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:04:13', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bf822240-14d7-4e22-942a-976218b33cbf'	System	06 Aug 2020 14:50:39
User entered 'None (0)'	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:04:15', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bf822240-14d7-4e22-942a-976218b33cbf'	System	06 Aug 2020 14:50:39
User entered 'None (0)'	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:04:20', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bf822240-14d7-4e22-942a-976218b33cbf'	System	06 Aug 2020 14:50:39
User entered 'No (N)'	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-03T21:04:23', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bf822240-14d7-4e22-942a-976218b33cbf'	System	06 Aug 2020 14:50:39
User entered '03 Aug 2020 21:04'	System	06 Aug 2020 14:50:39

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 7'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:39', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '30c5be5f-72c9-4e24-ba63-5c64ce459b86'	System	06 Aug 2020 14:50:41
User entered 'None (0)'	System	06 Aug 2020 14:50:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:41', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '30c5be5f-72c9-4e24-ba63-5c64ce459b86'	System	06 Aug 2020 14:50:41
User entered 'None (0)'	System	06 Aug 2020 14:50:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:43', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '30c5be5f-72c9-4e24-ba63-5c64ce459b86'	System	06 Aug 2020 14:50:41
User entered 'None (0)'	System	06 Aug 2020 14:50:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:45', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '30c5be5f-72c9-4e24-ba63-5c64ce459b86'	System	06 Aug 2020 14:50:41
User entered 'None (0)'	System	06 Aug 2020 14:50:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:47', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '30c5be5f-72c9-4e24-ba63-5c64ce459b86'	System	06 Aug 2020 14:50:41
User entered 'None (0)'	System	06 Aug 2020 14:50:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:49', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '30c5be5f-72c9-4e24-ba63-5c64ce459b86'	System	06 Aug 2020 14:50:41
User entered 'None (0)'	System	06 Aug 2020 14:50:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:53', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '30c5be5f-72c9-4e24-ba63-5c64ce459b86'	System	06 Aug 2020 14:50:41
User entered 'No (N)'	System	06 Aug 2020 14:50:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-04T21:13:56', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '30c5be5f-72c9-4e24-ba63-5c64ce459b86'	System	06 Aug 2020 14:50:41
User entered '04 Aug 2020 21:13'	System	06 Aug 2020 14:50:41

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:27:20

US3412016

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:33:50

US3412016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '05 Aug 2020'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:33:50

US3412016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Contact Made (CONTACT MADE)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:33:50

US3412016

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:33:50

US3412016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:38:00

US3412016

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'I'	System	26 Aug 2020 14:38:00

US3412016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:34:14

US3412016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '14 Aug 2020'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:34:14

US3412016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Contact Made (CONTACT MADE)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:34:14

US3412016

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:34:14

US3412016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:38:15

US3412016

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User entered 'I'	System	26 Aug 2020 14:38:15

US3412016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:35:27

US3412016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '19 Aug 2020'	Mylene Asmar-Rios	14 Sep 2020 17:35:27

US3412016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Contact Made (CONTACT MADE)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:35:27

US3412016

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:35:27

US3412016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:38:29

US3412016

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User entered 'I'	System	26 Aug 2020 14:38:29

US3412016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:39:15

US3412016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:39:15

US3412016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[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 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:39:15

US3412016

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'VISIT2'	System	26 Aug 2020 14:39:15

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User accepted default value 'Pre-Dose (PREDOSE)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '26 Aug 2020'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '10:03'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered '26 Aug 2020 10:03'	System	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '36.5' C	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '70'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'bpm'	System	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '18'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'breaths/min'	System	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '134'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'mmHg'	System	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '70'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'mmHg'	System	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User accepted default value 'Post-Dose (POSTDOSE)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '26 Aug 2020'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '11:26'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered '26 Aug 2020 11:26'	System	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '97.2' F	Mylene Asmar-Rios	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '72'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'bpm'	System	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '16'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'breaths/min'	System	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '140'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'mmHg'	System	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '78'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'mmHg'	System	14 Sep 2020 17:42:37

US3412016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:59

US3412016

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '26 Aug 2020'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:42:59

US3412016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:56:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:56:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

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 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:56:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 14:56:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '26 Aug 2020'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:56:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '10:55'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:56:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered '26 Aug 2020 10:55'	System	26 Aug 2020 14:56:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Left Arm (LEFT ARM)'	(b) (4) (b) (4), (b) (6)	26 Aug 2020 14:56:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'ONCE'	System	26 Aug 2020 14:56:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:26:23

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 14:56:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:43:26

US3412016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '26 Aug 2020'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:43:26

US3412016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '10:20'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:43:26

US3412016

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered '26 Aug 2020 10:20'	System	14 Sep 2020 17:43:26

US3412016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:26:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '26 Aug 2020'	Mylene Asmar-Rios	14 Sep 2020 17:43:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:43:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:43:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '10:25'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:43:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered '26 Aug 2020 10:25'	System	14 Sep 2020 17:43:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:23

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:43:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:43:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:23

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Mylene Asmar-Rios (b) (4)	14 Sep 2020 17:43:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered empty.	System	14 Sep 2020 17:43:48

US3412016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:53:14

US3412016

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'I'	System	02 Sep 2020 21:53:14

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:28:26', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '27b5601f-3f16-4a1e-83ff-cc1edc7f2a4e'	System	26 Aug 2020 15:30:21
User entered 'Yes (Y)'	System	26 Aug 2020 15:30:21

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:29:30', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '27b5601f-3f16-4a1e-83ff-cc1edc7f2a4e' User entered '97.2'	System	26 Aug 2020 15:30:21
	System	26 Aug 2020 15:30:21

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:30:13', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '27b5601f-3f16-4a1e-83ff-cc1edc7f2a4e'	System	26 Aug 2020 15:30:21
User entered 'No (N)'	System	26 Aug 2020 15:30:21

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:30:18', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '27b5601f-3f16-4a1e-83ff-cc1edc7f2a4e'	System	26 Aug 2020 15:30:21
User entered '26 Aug 2020 11:30'	System	26 Aug 2020 15:30:21

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '26 Aug 2020 11:15'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '26 Aug 2020 13:45'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:40:25', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ce15b8ef-99f5-4b1e-9128-c8bec9d8150c'	System	26 Aug 2020 18:40:44
User entered 'Yes (Y)'	System	26 Aug 2020 18:40:44

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:40:33', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ce15b8ef-99f5-4b1e-9128-c8bec9d8150c' User entered '97.2'	System	26 Aug 2020 18:40:44
	System	26 Aug 2020 18:40:44

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:40:37', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ce15b8ef-99f5-4b1e-9128-c8bec9d8150c'	System	26 Aug 2020 18:40:44
User entered 'No (N)'	System	26 Aug 2020 18:40:44

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:40:42', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ce15b8ef-99f5-4b1e-9128-c8bec9d8150c'	System	26 Aug 2020 18:40:44
User entered '26 Aug 2020 14:40'	System	26 Aug 2020 18:40:44

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '26 Aug 2020 14:40'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 2'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:08:23', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'dd0c2228-a59d-4c49-a842-53690276fd2b' User entered 'Yes (Y)'	System	27 Aug 2020 16:08:53
	System	27 Aug 2020 16:08:53

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:08:29', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'dd0c2228-a59d-4c49-a842-53690276fd2b' User entered '96.2'	System	27 Aug 2020 16:08:53
	System	27 Aug 2020 16:08:53

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:08:35', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'dd0c2228-a59d-4c49-a842-53690276fd2b'	System	27 Aug 2020 16:08:53
User entered 'No (N)'	System	27 Aug 2020 16:08:53

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:08:39', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'dd0c2228-a59d-4c49-a842-53690276fd2b' User entered '27 Aug 2020 12:08'	System	27 Aug 2020 16:08:53
	System	27 Aug 2020 16:08:53

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 3'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:08:27', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'cd9260b8-fc46-4e5c-b49d-7cc1263e4cca' User entered 'Yes (Y)'	System	29 Aug 2020 01:09:03
	System	29 Aug 2020 01:09:03

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:08:34', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'cd9260b8-fc46-4e5c-b49d-7cc1263e4cca' User entered '98.1'	System	29 Aug 2020 01:09:03
	System	29 Aug 2020 01:09:03

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:08:38', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'cd9260b8-fc46-4e5c-b49d-7cc1263e4cca' User entered 'No (N)'	System	29 Aug 2020 01:09:03
	System	29 Aug 2020 01:09:03

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:08:42', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'cd9260b8-fc46-4e5c-b49d-7cc1263e4cca' User entered '28 Aug 2020 21:08'	System	29 Aug 2020 01:09:03
	System	29 Aug 2020 01:09:03

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 4'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:41:19', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'a9742f1f-b999-4bd3-9486-fedd1c7bb223' User entered 'Yes (Y)'	System	30 Aug 2020 03:41:36
	System	30 Aug 2020 03:41:36

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:41:26', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'a9742f1f-b999-4bd3-9486-fedd1c7bb223' User entered '97.2'	System	30 Aug 2020 03:41:36
	System	30 Aug 2020 03:41:36

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:41:31', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'a9742f1f-b999-4bd3-9486-fedd1c7bb223'	System	30 Aug 2020 03:41:36
User entered 'No (N)'	System	30 Aug 2020 03:41:36

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:41:34', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'a9742f1f-b999-4bd3-9486-fedd1c7bb223' User entered '29 Aug 2020 23:41'	System	30 Aug 2020 03:41:36
	System	30 Aug 2020 03:41:36

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 5'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:14:17', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '935dc7a4-586b-48e6-8371-bb6024d9b54b'	System	30 Aug 2020 23:14:37
User entered 'Yes (Y)'	System	30 Aug 2020 23:14:37

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:14:25', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '935dc7a4-586b-48e6-8371-bb6024d9b54b' User entered '96.5'	System	30 Aug 2020 23:14:37
	System	30 Aug 2020 23:14:37

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:14:28', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '935dc7a4-586b-48e6-8371-bb6024d9b54b'	System	30 Aug 2020 23:14:37
User entered 'No (N)'	System	30 Aug 2020 23:14:37

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:14:31', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '935dc7a4-586b-48e6-8371-bb6024d9b54b' User entered '30 Aug 2020 19:14'	System	30 Aug 2020 23:14:37
	System	30 Aug 2020 23:14:37

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 6'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:24:35', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fcff9f0a-bd9c-409b-b7ca-18643a6b4c51' User entered 'Yes (Y)'	System	01 Sep 2020 12:24:52
	System	01 Sep 2020 12:24:52

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:24:41', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fcff9f0a-bd9c-409b-b7ca-18643a6b4c51' User entered '96.5'	System	01 Sep 2020 12:24:52
	System	01 Sep 2020 12:24:52

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:24:45', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fcff9f0a-bd9c-409b-b7ca-18643a6b4c51'	System	01 Sep 2020 12:24:52
User entered 'No (N)'	System	01 Sep 2020 12:24:52

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:24:48', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fcff9f0a-bd9c-409b-b7ca-18643a6b4c51'	System	01 Sep 2020 12:24:52
User entered '01 Sep 2020 08:24'	System	01 Sep 2020 12:24:52

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 7'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:30:36', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '0f866d55-14a4-4f31-a610-e81f0a3d36ec' User entered 'None (1)'	System	26 Aug 2020 15:30:54
	System	26 Aug 2020 15:30:54

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:30:40', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '0f866d55-14a4-4f31-a610-e81f0a3d36ec'	System	26 Aug 2020 15:30:54
User entered 'No (N)'	System	26 Aug 2020 15:30:54

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:30:44', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '0f866d55-14a4-4f31-a610-e81f0a3d36ec'	System	26 Aug 2020 15:30:54
User entered 'No (N)'	System	26 Aug 2020 15:30:54

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:30:47', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '0f866d55-14a4-4f31-a610-e81f0a3d36ec' User entered 'None (1)'	System	26 Aug 2020 15:30:54
	System	26 Aug 2020 15:30:54

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:30:50', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '0f866d55-14a4-4f31-a610-e81f0a3d36ec'	System	26 Aug 2020 15:30:54
User entered '26 Aug 2020 11:30'	System	26 Aug 2020 15:30:54

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '26 Aug 2020 11:15'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '26 Aug 2020 13:45'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:40:50', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'da73119e-277f-4c78-b7de-d8a8524b958e' User entered 'None (1)'	System	26 Aug 2020 18:41:05
	System	26 Aug 2020 18:41:05

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:40:53', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'da73119e-277f-4c78-b7de-d8a8524b958e' User entered 'No (N)'	System	26 Aug 2020 18:41:05
	System	26 Aug 2020 18:41:05

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:40:56', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'da73119e-277f-4c78-b7de-d8a8524b958e' User entered 'No (N)'	System	26 Aug 2020 18:41:05
	System	26 Aug 2020 18:41:05

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:40:57', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'da73119e-277f-4c78-b7de-d8a8524b958e' User entered 'None (1)'	System	26 Aug 2020 18:41:05
	System	26 Aug 2020 18:41:05

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:41:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'da73119e-277f-4c78-b7de-d8a8524b958e' User entered '26 Aug 2020 14:41'	System	26 Aug 2020 18:41:05
	System	26 Aug 2020 18:41:05

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '26 Aug 2020 14:40'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 2'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:08:51', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c648ab96-ac35-4b04-8834-e126563dd63f' User entered 'None (1)'	System	27 Aug 2020 16:09:15
	System	27 Aug 2020 16:09:15

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c648ab96-ac35-4b04-8834-e126563dd63f' User entered 'No (N)'	System	27 Aug 2020 16:09:15
	System	27 Aug 2020 16:09:15

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:07', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c648ab96-ac35-4b04-8834-e126563dd63f' User entered 'No (N)'	System	27 Aug 2020 16:09:15
	System	27 Aug 2020 16:09:15

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:11', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c648ab96-ac35-4b04-8834-e126563dd63f' User entered 'None (1)'	System	27 Aug 2020 16:09:15
	System	27 Aug 2020 16:09:15

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:13', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c648ab96-ac35-4b04-8834-e126563dd63f' User entered '27 Aug 2020 12:09'	System	27 Aug 2020 16:09:15
	System	27 Aug 2020 16:09:15

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 3'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:06', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '82e9fc9e-6a44-4d48-8002-19f332c7df57'	System	29 Aug 2020 01:06:19
User entered 'None (1)'	System	29 Aug 2020 01:06:19

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:11', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '82e9fc9e-6a44-4d48-8002-19f332c7df57'	System	29 Aug 2020 01:06:19
User entered 'No (N)'	System	29 Aug 2020 01:06:19

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:13', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '82e9fc9e-6a44-4d48-8002-19f332c7df57'	System	29 Aug 2020 01:06:19
User entered 'No (N)'	System	29 Aug 2020 01:06:19

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:15', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '82e9fc9e-6a44-4d48-8002-19f332c7df57'	System	29 Aug 2020 01:06:19
User entered 'None (1)'	System	29 Aug 2020 01:06:19

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:18', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '82e9fc9e-6a44-4d48-8002-19f332c7df57'	System	29 Aug 2020 01:06:19
User entered '28 Aug 2020 21:06'	System	29 Aug 2020 01:06:19

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 4'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:41:39', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7a350c48-d6f9-4cbf-aa4d-1f5428db1c18'	System	30 Aug 2020 03:41:56
User entered 'None (1)'	System	30 Aug 2020 03:41:56

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:41:43', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7a350c48-d6f9-4cbf-aa4d-1f5428db1c18'	System	30 Aug 2020 03:41:56
User entered 'No (N)'	System	30 Aug 2020 03:41:56

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:41:47', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7a350c48-d6f9-4cbf-aa4d-1f5428db1c18'	System	30 Aug 2020 03:41:56
User entered 'No (N)'	System	30 Aug 2020 03:41:56

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:41:49', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7a350c48-d6f9-4cbf-aa4d-1f5428db1c18' User entered 'None (1)'	System	30 Aug 2020 03:41:56
	System	30 Aug 2020 03:41:56

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:41:52', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7a350c48-d6f9-4cbf-aa4d-1f5428db1c18'	System	30 Aug 2020 03:41:56
User entered '29 Aug 2020 23:41'	System	30 Aug 2020 03:41:56

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 5'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:13:38', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '55386147-afa5-411b-9107-1944c4fc7dbc' User entered 'None (1)'	System	30 Aug 2020 23:13:53
	System	30 Aug 2020 23:13:53

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:13:43', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '55386147-afa5-411b-9107-1944c4fc7dbc' User entered 'No (N)'	System	30 Aug 2020 23:13:53
	System	30 Aug 2020 23:13:53

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:13:45', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '55386147-afa5-411b-9107-1944c4fc7dbc' User entered 'No (N)'	System	30 Aug 2020 23:13:53
	System	30 Aug 2020 23:13:53

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:13:47', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '55386147-afa5-411b-9107-1944c4fc7dbc' User entered 'None (1)'	System	30 Aug 2020 23:13:53
	System	30 Aug 2020 23:13:53

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:13:50', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '55386147-afa5-411b-9107-1944c4fc7dbc' User entered '30 Aug 2020 19:13'	System	30 Aug 2020 23:13:53
	System	30 Aug 2020 23:13:53

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 6'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:24:54', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '4721e2e8-0bf3-4073-ae9a-af844b7c1cf0' User entered 'None (1)'	System	01 Sep 2020 12:25:09
	System	01 Sep 2020 12:25:09

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:24:59', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '4721e2e8-0bf3-4073-ae9a-af844b7c1cf0' User entered 'No (N)'	System	01 Sep 2020 12:25:09
	System	01 Sep 2020 12:25:09

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:25:03', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '4721e2e8-0bf3-4073-ae9a-af844b7c1cf0' User entered 'No (N)'	System	01 Sep 2020 12:25:09
	System	01 Sep 2020 12:25:09

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:25:05', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '4721e2e8-0bf3-4073-ae9a-af844b7c1cf0'	System	01 Sep 2020 12:25:09
User entered 'None (1)'	System	01 Sep 2020 12:25:09

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:25:07', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '4721e2e8-0bf3-4073-ae9a-af844b7c1cf0'	System	01 Sep 2020 12:25:09
User entered '01 Sep 2020 08:25'	System	01 Sep 2020 12:25:09

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 7'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:30:55', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '415eb0d3-a877-4f2e-a808-b318c7e75bbe' User entered 'None (0)'	System	26 Aug 2020 15:31:19
	System	26 Aug 2020 15:31:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:30:57', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '415eb0d3-a877-4f2e-a808-b318c7e75bbe' User entered 'None (0)'	System	26 Aug 2020 15:31:19
	System	26 Aug 2020 15:31:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:30:59', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '415eb0d3-a877-4f2e-a808-b318c7e75bbe' User entered 'None (0)'	System	26 Aug 2020 15:31:19
	System	26 Aug 2020 15:31:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:31:01', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '415eb0d3-a877-4f2e-a808-b318c7e75bbe' User entered 'None (0)'	System	26 Aug 2020 15:31:19
	System	26 Aug 2020 15:31:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:31:03', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '415eb0d3-a877-4f2e-a808-b318c7e75bbe' User entered 'None (0)'	System	26 Aug 2020 15:31:19
	System	26 Aug 2020 15:31:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:31:05', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '415eb0d3-a877-4f2e-a808-b318c7e75bbe' User entered 'None (0)'	System	26 Aug 2020 15:31:19
	System	26 Aug 2020 15:31:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:31:14', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '415eb0d3-a877-4f2e-a808-b318c7e75bbe' User entered 'No (N)'	System	26 Aug 2020 15:31:19
	System	26 Aug 2020 15:31:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T11:31:16', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '415eb0d3-a877-4f2e-a808-b318c7e75bbe' User entered '26 Aug 2020 11:31'	System	26 Aug 2020 15:31:19
	System	26 Aug 2020 15:31:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '26 Aug 2020 11:15'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '26 Aug 2020 13:45'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:41:06', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'e72821e6-2312-44d2-b23b-acf4069bfa04' User entered 'None (0)'	System	26 Aug 2020 18:41:47
	System	26 Aug 2020 18:41:47

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:41:08', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'e72821e6-2312-44d2-b23b-acf4069bfa04' User entered 'None (0)'	System	26 Aug 2020 18:41:47
	System	26 Aug 2020 18:41:47

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:41:11', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'e72821e6-2312-44d2-b23b-acf4069bfa04' User entered 'None (0)'	System	26 Aug 2020 18:41:47
	System	26 Aug 2020 18:41:47

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:41:14', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'e72821e6-2312-44d2-b23b-acf4069bfa04' User entered 'None (0)'	System	26 Aug 2020 18:41:47
	System	26 Aug 2020 18:41:47

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:41:16', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'e72821e6-2312-44d2-b23b-acf4069bfa04' User entered 'None (0)'	System	26 Aug 2020 18:41:47
	System	26 Aug 2020 18:41:47

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:41:18', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'e72821e6-2312-44d2-b23b-acf4069bfa04' User entered 'None (0)'	System	26 Aug 2020 18:41:47
	System	26 Aug 2020 18:41:47

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:41:27', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'e72821e6-2312-44d2-b23b-acf4069bfa04'	System	26 Aug 2020 18:41:47
User entered 'No (N)'	System	26 Aug 2020 18:41:47

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-26T14:41:29', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'e72821e6-2312-44d2-b23b-acf4069bfa04' User entered '26 Aug 2020 14:41'	System	26 Aug 2020 18:41:47
	System	26 Aug 2020 18:41:47

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '26 Aug 2020 14:40'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 2'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:20', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ddc073c2-b91e-4184-a834-f625482bdb1e' User entered 'None (0)'	System	27 Aug 2020 16:10:06
	System	27 Aug 2020 16:10:06

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:24', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ddc073c2-b91e-4184-a834-f625482bdb1e' User entered 'None (0)'	System	27 Aug 2020 16:10:06
	System	27 Aug 2020 16:10:06

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:33', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ddc073c2-b91e-4184-a834-f625482bdb1e' User entered 'None (0)'	System	27 Aug 2020 16:10:06
	System	27 Aug 2020 16:10:06

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:47', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ddc073c2-b91e-4184-a834-f625482bdb1e' User entered 'None (0)'	System	27 Aug 2020 16:10:06
	System	27 Aug 2020 16:10:06

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:50', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ddc073c2-b91e-4184-a834-f625482bdb1e' User entered 'None (0)'	System	27 Aug 2020 16:10:06
	System	27 Aug 2020 16:10:06

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:53', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ddc073c2-b91e-4184-a834-f625482bdb1e' User entered 'None (0)'	System	27 Aug 2020 16:10:06
	System	27 Aug 2020 16:10:06

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:56', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ddc073c2-b91e-4184-a834-f625482bdb1e' User entered 'No (N)'	System	27 Aug 2020 16:10:06
	System	27 Aug 2020 16:10:06

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-27T12:09:59', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'ddc073c2-b91e-4184-a834-f625482bdb1e' User entered '27 Aug 2020 12:09'	System	27 Aug 2020 16:10:06
	System	27 Aug 2020 16:10:06

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 3'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:22', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bde9070f-a75d-4e5c-aec0-24e764d621cb' User entered 'None (0)'	System	29 Aug 2020 01:06:39
	System	29 Aug 2020 01:06:39

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:24', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bde9070f-a75d-4e5c-aec0-24e764d621cb' User entered 'None (0)'	System	29 Aug 2020 01:06:39
	System	29 Aug 2020 01:06:39

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:26', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bde9070f-a75d-4e5c-aec0-24e764d621cb' User entered 'None (0)'	System	29 Aug 2020 01:06:39
	System	29 Aug 2020 01:06:39

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:28', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bde9070f-a75d-4e5c-aec0-24e764d621cb' User entered 'None (0)'	System	29 Aug 2020 01:06:39
	System	29 Aug 2020 01:06:39

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:30', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bde9070f-a75d-4e5c-aec0-24e764d621cb' User entered 'None (0)'	System	29 Aug 2020 01:06:39
	System	29 Aug 2020 01:06:39

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:32', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bde9070f-a75d-4e5c-aec0-24e764d621cb' User entered 'None (0)'	System	29 Aug 2020 01:06:39
	System	29 Aug 2020 01:06:39

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:34', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bde9070f-a75d-4e5c-aec0-24e764d621cb' User entered 'No (N)'	System	29 Aug 2020 01:06:39
	System	29 Aug 2020 01:06:39

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-28T21:06:37', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'bde9070f-a75d-4e5c-aec0-24e764d621cb' User entered '28 Aug 2020 21:06'	System	29 Aug 2020 01:06:39
	System	29 Aug 2020 01:06:39

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 4'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:41:56', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '38df2206-3a3f-4462-92f4-850f82c8d026'	System	30 Aug 2020 03:42:19
User entered 'None (0)'	System	30 Aug 2020 03:42:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:41:58', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '38df2206-3a3f-4462-92f4-850f82c8d026'	System	30 Aug 2020 03:42:19
User entered 'None (0)'	System	30 Aug 2020 03:42:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:42:02', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '38df2206-3a3f-4462-92f4-850f82c8d026'	System	30 Aug 2020 03:42:19
User entered 'None (0)'	System	30 Aug 2020 03:42:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:42:05', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '38df2206-3a3f-4462-92f4-850f82c8d026'	System	30 Aug 2020 03:42:19
User entered 'None (0)'	System	30 Aug 2020 03:42:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:42:07', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '38df2206-3a3f-4462-92f4-850f82c8d026'	System	30 Aug 2020 03:42:19
User entered 'None (0)'	System	30 Aug 2020 03:42:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:42:10', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '38df2206-3a3f-4462-92f4-850f82c8d026'	System	30 Aug 2020 03:42:19
User entered 'None (0)'	System	30 Aug 2020 03:42:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:42:15', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '38df2206-3a3f-4462-92f4-850f82c8d026'	System	30 Aug 2020 03:42:19
User entered 'No (N)'	System	30 Aug 2020 03:42:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-29T23:42:18', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '38df2206-3a3f-4462-92f4-850f82c8d026'	System	30 Aug 2020 03:42:19
User entered '29 Aug 2020 23:42'	System	30 Aug 2020 03:42:19

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 5'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:13:54', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6f35fd08-c2a2-4979-87c5-6036c02c595f' User entered 'None (0)'	System	30 Aug 2020 23:14:13
	System	30 Aug 2020 23:14:13

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:13:56', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6f35fd08-c2a2-4979-87c5-6036c02c595f' User entered 'None (0)'	System	30 Aug 2020 23:14:13
	System	30 Aug 2020 23:14:13

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:13:58', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6f35fd08-c2a2-4979-87c5-6036c02c595f' User entered 'None (0)'	System	30 Aug 2020 23:14:13
	System	30 Aug 2020 23:14:13

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:14:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6f35fd08-c2a2-4979-87c5-6036c02c595f' User entered 'None (0)'	System	30 Aug 2020 23:14:13
	System	30 Aug 2020 23:14:13

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:14:02', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6f35fd08-c2a2-4979-87c5-6036c02c595f' User entered 'None (0)'	System	30 Aug 2020 23:14:13
	System	30 Aug 2020 23:14:13

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:14:03', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6f35fd08-c2a2-4979-87c5-6036c02c595f' User entered 'None (0)'	System	30 Aug 2020 23:14:13
	System	30 Aug 2020 23:14:13

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:14:06', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6f35fd08-c2a2-4979-87c5-6036c02c595f' User entered 'No (N)'	System	30 Aug 2020 23:14:13
	System	30 Aug 2020 23:14:13

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-08-30T19:14:09', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6f35fd08-c2a2-4979-87c5-6036c02c595f' User entered '30 Aug 2020 19:14'	System	30 Aug 2020 23:14:13
	System	30 Aug 2020 23:14:13

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 6'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:25:11', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '47f90c0a-f010-4c8f-a1df-e90b6f56af1f' User entered 'None (0)'	System	01 Sep 2020 12:25:31
	System	01 Sep 2020 12:25:31

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:25:14', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '47f90c0a-f010-4c8f-a1df-e90b6f56af1f' User entered 'None (0)'	System	01 Sep 2020 12:25:31
	System	01 Sep 2020 12:25:31

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:25:15', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '47f90c0a-f010-4c8f-a1df-e90b6f56af1f' User entered 'None (0)'	System	01 Sep 2020 12:25:31
	System	01 Sep 2020 12:25:31

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:25:17', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '47f90c0a-f010-4c8f-a1df-e90b6f56af1f' User entered 'None (0)'	System	01 Sep 2020 12:25:31
	System	01 Sep 2020 12:25:31

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:25:19', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '47f90c0a-f010-4c8f-a1df-e90b6f56af1f' User entered 'None (0)'	System	01 Sep 2020 12:25:31
	System	01 Sep 2020 12:25:31

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:25:21', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '47f90c0a-f010-4c8f-a1df-e90b6f56af1f' User entered 'None (0)'	System	01 Sep 2020 12:25:31
	System	01 Sep 2020 12:25:31

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:25:26', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '47f90c0a-f010-4c8f-a1df-e90b6f56af1f' User entered 'No (N)'	System	01 Sep 2020 12:25:31
	System	01 Sep 2020 12:25:31

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-01T08:25:28', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '47f90c0a-f010-4c8f-a1df-e90b6f56af1f' User entered '01 Sep 2020 08:25'	System	01 Sep 2020 12:25:31
	System	01 Sep 2020 12:25:31

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	26 Aug 2020 14:56:48
User entered 'Day 7'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

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 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 14:56:48

US3412016

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:26:23

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 14:56:48

US3412016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:53:32

US3412016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered '02 Sep 2020'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:53:32

US3412016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:53:32

US3412016

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered empty.	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:53:32

US3412016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:24
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	02 Sep 2020 21:53:37

US3412016

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User entered 'I'	System	02 Sep 2020 21:53:37

US3412016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Sep 2020 20:30:27

US3412016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '9 Sep 2020'	Mason Urban (b) (4)	09 Sep 2020 20:30:27

US3412016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	09 Sep 2020 20:30:27

US3412016

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Mason Urban (b) (4)	09 Sep 2020 20:30:27

US3412016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Mason Urban (b) (4)	09 Sep 2020 20:31:30

US3412016

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User entered 'I'	System	09 Sep 2020 20:31:30

US3412016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Mason Urban (b) (4)	16 Sep 2020 18:13:37

US3412016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '16 Sep 2020'	Mason Urban (b) (4)	16 Sep 2020 18:13:37

US3412016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	16 Sep 2020 18:13:37

US3412016

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Mason Urban (b) (4)	16 Sep 2020 18:13:37

US3412016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Mason Urban (b) (4)	16 Sep 2020 18:13:43

US3412016

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:35
User entered 'I'	System	16 Sep 2020 18:13:43

US3412016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	29 Sep 2020 17:24:16

US3412016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '23 Sep 2020'	Jacob sekinger (b) (4)	29 Sep 2020 17:24:16

US3412016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[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 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Clinic (Clinic)'	Jacob sekinger (b) (4)	29 Sep 2020 17:24:16

US3412016

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'VISIT3'	System	29 Sep 2020 17:24:16

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'No (N)'	Jacob sekinger (b) (4)	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered empty.	System	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered empty.	System	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered empty.	System	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered empty.	System	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty.	Jacob sekinger (b) (4)	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered empty.	System	29 Sep 2020 17:24:25

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Height (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57

US3412016

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57

US3412016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	04 Nov 2020 21:08:19
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	29 Sep 2020 17:24:35

US3412016

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered empty; reason for change Data Entry Error	Melissa Fuson (b) (4)	04 Nov 2020 21:08:19
User entered '23 Sep 2020'	Jacob sekinger (b) (4)	29 Sep 2020 17:24:35

US3412016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	29 Sep 2020 17:24:53

US3412016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '23 Sep 2020'	Jacob sekinger (b) (4)	29 Sep 2020 17:24:53

US3412016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered '9:30'	Jacob sekinger (b) (4)	29 Sep 2020 17:24:53

US3412016

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered '23 Sep 2020 9:30'	System	29 Sep 2020 17:24:53

US3412016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:56
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	29 Sep 2020 17:25:09

US3412016

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'I'	System	29 Sep 2020 17:25:09

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 64'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-30T21:25:41', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'd56e3889-0e69-4159-961e-3b4ebb4f711b' User entered 'No (N)'	System	01 Oct 2020 01:25:59
	System	01 Oct 2020 01:25:59

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Have you been exposed to someone with 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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-30T21:25:49', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'd56e3889-0e69-4159-961e-3b4ebb4f711b' User entered 'No (N)'	System	01 Oct 2020 01:25:59
	System	01 Oct 2020 01:25:59

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-09-30T21:25:54', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'd56e3889-0e69-4159-961e-3b4ebb4f711b' User entered '30 Sep 2020 21:25:54'	System	01 Oct 2020 01:25:59
	System	01 Oct 2020 01:25:59

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 71'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-10-05T18:10:03', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '1cf7206b-f45e-4d55-8965-e8ccb5db430f' User entered 'No (N)'	System	05 Oct 2020 22:10:15
	System	05 Oct 2020 22:10:15

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-10-05T18:10:09', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '1cf7206b-f45e-4d55-8965-e8ccb5db430f' User entered 'No (N)'	System	05 Oct 2020 22:10:15
	System	05 Oct 2020 22:10:15

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-10-05T18:10:12', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '1cf7206b-f45e-4d55-8965-e8ccb5db430f' User entered '05 Oct 2020 18:10:12'	System	05 Oct 2020 22:10:15
	System	05 Oct 2020 22:10:15

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 78'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-10-12T09:24:01', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f45c3c32-5988-48d1-b62f-e1b5572fe630'	System	12 Oct 2020 13:24:09
User entered 'No (N)'	System	12 Oct 2020 13:24:09

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-10-12T09:24:03', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f45c3c32-5988-48d1-b62f-e1b5572fe630'	System	12 Oct 2020 13:24:09
User entered 'No (N)'	System	12 Oct 2020 13:24:09

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-10-12T09:24:08', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f45c3c32-5988-48d1-b62f-e1b5572fe630' User entered '12 Oct 2020 09:24:08'	System	12 Oct 2020 13:24:09
	System	12 Oct 2020 13:24:09

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 92'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-10-26T13:52:20', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'dcf16edd-5797-49b1-b345-f0be2d57d87f' User entered 'No (N)'	System	26 Oct 2020 17:52:31
	System	26 Oct 2020 17:52:31

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-10-26T13:52:22', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'dcf16edd-5797-49b1-b345-f0be2d57d87f' User entered 'No (N)'	System	26 Oct 2020 17:52:31
	System	26 Oct 2020 17:52:31

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-10-26T13:52:27', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'dcf16edd-5797-49b1-b345-f0be2d57d87f' User entered '26 Oct 2020 13:52:27'	System	26 Oct 2020 17:52:31
	System	26 Oct 2020 17:52:31

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 99'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-03T01:04:58', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '36752b04-527b-4757-9add-8e3f4d3560cb' User entered 'No (N)'	System	03 Nov 2020 06:05:08
	System	03 Nov 2020 06:05:08

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-03T01:05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '36752b04-527b-4757-9add-8e3f4d3560cb' User entered 'No (N)'	System	03 Nov 2020 06:05:08
	System	03 Nov 2020 06:05:08

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-03T01:05:05', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '36752b04-527b-4757-9add-8e3f4d3560cb' User entered '03 Nov 2020 01:05:05'	System	03 Nov 2020 06:05:08
	System	03 Nov 2020 06:05:08

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 106'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-09T21:19:54', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '752099db-d89d-4b50-86ca-4e42cacd5da0' User entered 'No (N)'	System	10 Nov 2020 02:20:03
	System	10 Nov 2020 02:20:03

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-09T21:19:56', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '752099db-d89d-4b50-86ca-4e42cacd5da0'	System	10 Nov 2020 02:20:03
User entered 'No (N)'	System	10 Nov 2020 02:20:03

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-09T21:19:59', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '752099db-d89d-4b50-86ca-4e42cacd5da0' User entered '09 Nov 2020 21:19:59'	System	10 Nov 2020 02:20:03
	System	10 Nov 2020 02:20:03

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '09 Nov 2020 00:01'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '13 Nov 2020 23:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered 'Day 113'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-16T17:44:30', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '3f74565f-ca87-4aaf-8b64-fac9888d1564' User entered 'No (N)'	System	16 Nov 2020 22:44:38
	System	16 Nov 2020 22:44:38

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Have you been exposed to someone with 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 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-16T17:44:32', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '3f74565f-ca87-4aaf-8b64-fac9888d1564'	System	16 Nov 2020 22:44:38
User entered 'No (N)'	System	16 Nov 2020 22:44:38

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-16T17:44:37', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '3f74565f-ca87-4aaf-8b64-fac9888d1564' User entered '16 Nov 2020 17:44:37'	System	16 Nov 2020 22:44:38
	System	16 Nov 2020 22:44:38

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '16 Nov 2020 00:01'	System	29 Jul 2020 17:27:20

US3412016

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:26:02
Data entry locked.	System	29 Jul 2020 17:27:20
User entered '20 Nov 2020 23:59'	System	29 Jul 2020 17:27:20

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-20T10:00:25', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '8952742c-b0f8-469a-95e7-a1a56d1aac13' User entered 'No (N)'	System	20 Nov 2020 15:00:37
	System	20 Nov 2020 15:00:37

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-20T10:00:28', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '8952742c-b0f8-469a-95e7-a1a56d1aac13' User entered 'No (N)'	System	20 Nov 2020 15:00:37

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-20T10:00:30', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '8952742c-b0f8-469a-95e7-a1a56d1aac13' User entered '20 Nov 2020 10:00:30'	System	20 Nov 2020 15:00:37
	System	20 Nov 2020 15:00:37

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-28T22:00:06', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '1ed20db6-7837-43f7-a90c-3805c77c7cdb' User entered 'No (N)'	System	29 Nov 2020 03:00:15
	System	29 Nov 2020 03:00:15

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-28T22:00:08', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '1ed20db6-7837-43f7-a90c-3805c77c7cdb' User entered 'No (N)'	System	29 Nov 2020 03:00:15

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-11-28T22:00:11', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '1ed20db6-7837-43f7-a90c-3805c77c7cdb' User entered '28 Nov 2020 22:00:11'	System	29 Nov 2020 03:00:15
	System	29 Nov 2020 03:00:15

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-07T04:43:16', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '9b8f278e-5e8d-483c-829c-64d4e9ec98a7'	System	07 Dec 2020 09:43:28
User entered 'No (N)'	System	07 Dec 2020 09:43:28

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-07T04:43:18', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '9b8f278e-5e8d-483c-829c-64d4e9ec98a7'	System	07 Dec 2020 09:43:28
User entered 'No (N)'	System	07 Dec 2020 09:43:28

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-07T04:43:24', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '9b8f278e-5e8d-483c-829c-64d4e9ec98a7' User entered '07 Dec 2020 04:43:24'	System	07 Dec 2020 09:43:28
	System	07 Dec 2020 09:43:28

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-12T06:03:44', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '619ec2b7-eaee-453b-9302-368526d69260'	System	12 Dec 2020 11:03:52
User entered 'No (N)'	System	12 Dec 2020 11:03:52

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-12T06:03:46', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '619ec2b7-eaee-453b-9302-368526d69260'	System	12 Dec 2020 11:03:52
User entered 'No (N)'	System	12 Dec 2020 11:03:52

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-12T06:03:50', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '619ec2b7-eaee-453b-9302-368526d69260' User entered '12 Dec 2020 06:03:50'	System	12 Dec 2020 11:03:52
	System	12 Dec 2020 11:03:52

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-18T17:12:14', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '066935ff-359c-4430-9279-10d00582863f' User entered 'No (N)'	System	18 Dec 2020 22:12:25
	System	18 Dec 2020 22:12:25

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-18T17:12:16', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '066935ff-359c-4430-9279-10d00582863f' User entered 'No (N)'	System	18 Dec 2020 22:12:25
	System	18 Dec 2020 22:12:25

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-18T17:12:21', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '066935ff-359c-4430-9279-10d00582863f' User entered '18 Dec 2020 17:12:21'	System	18 Dec 2020 22:12:25
	System	18 Dec 2020 22:12:25

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-25T14:15:28', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '368528c3-504c-4177-86ea-39047ab8c519' User entered 'No (N)'	System	25 Dec 2020 19:15:38
	System	25 Dec 2020 19:15:38

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-25T14:15:30', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '368528c3-504c-4177-86ea-39047ab8c519'	System	25 Dec 2020 19:15:38
User entered 'No (N)'	System	25 Dec 2020 19:15:38

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2020-12-25T14:15:34', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '368528c3-504c-4177-86ea-39047ab8c519' User entered '25 Dec 2020 14:15:34'	System	25 Dec 2020 19:15:38
	System	25 Dec 2020 19:15:38

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-01T15:43:28', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'cf75990a-33ca-4dbe-a305-44893f9f2ab3' User entered 'No (N)'	System	01 Jan 2021 20:43:36
	System	01 Jan 2021 20:43:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-01T15:43:30', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'cf75990a-33ca-4dbe-a305-44893f9f2ab3'	System	01 Jan 2021 20:43:36
User entered 'No (N)'	System	01 Jan 2021 20:43:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-01T15:43:33', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'cf75990a-33ca-4dbe-a305-44893f9f2ab3' User entered '01 Jan 2021 15:43:33'	System	01 Jan 2021 20:43:36
	System	01 Jan 2021 20:43:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-10T12:02:21', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '4944bc99-18b6-491c-881e-7ea670ec37e6' User entered 'No (N)'	System	10 Jan 2021 17:02:49
	System	10 Jan 2021 17:02:49

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-10T12:02:24', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '4944bc99-18b6-491c-881e-7ea670ec37e6'	System	10 Jan 2021 17:02:49
User entered 'No (N)'	System	10 Jan 2021 17:02:49

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-10T12:02:27', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '4944bc99-18b6-491c-881e-7ea670ec37e6' User entered '10 Jan 2021 12:02:27'	System	10 Jan 2021 17:02:49
	System	10 Jan 2021 17:02:49

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-15T13:39:42', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c8321d61-6642-4ff7-b15f-f6f845d0660e' User entered 'No (N)'	System	15 Jan 2021 18:39:52
	System	15 Jan 2021 18:39:52

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-15T13:39:44', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c8321d61-6642-4ff7-b15f-f6f845d0660e' User entered 'No (N)'	System	15 Jan 2021 18:39:52

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-15T13:39:48', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'c8321d61-6642-4ff7-b15f-f6f845d0660e' User entered '15 Jan 2021 13:39:48'	System	15 Jan 2021 18:39:52

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-22T00:26:33', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f0243612-30b8-4b45-855c-4b77de4f4cfa' User entered 'No (N)'	System	22 Jan 2021 05:26:43

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-22T00:26:35', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f0243612-30b8-4b45-855c-4b77de4f4cfa' User entered 'No (N)'	System	22 Jan 2021 05:26:43

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-22T00:26:38', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f0243612-30b8-4b45-855c-4b77de4f4cfa' User entered '22 Jan 2021 00:26:38'	System	22 Jan 2021 05:26:43
	System	22 Jan 2021 05:26:43

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-29T11:11:25', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6571ebc4-2001-44d5-b386-d2616c7406e7' User entered 'No (N)'	System	29 Jan 2021 16:11:35

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-29T11:11:27', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6571ebc4-2001-44d5-b386-d2616c7406e7'	System	29 Jan 2021 16:11:35
User entered 'No (N)'	System	29 Jan 2021 16:11:35

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-01-29T11:11:32', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6571ebc4-2001-44d5-b386-d2616c7406e7' User entered '29 Jan 2021 11:11:32'	System	29 Jan 2021 16:11:35

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-05T00:05:54', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '21442682-a84c-4cf5-9ad3-49dfff964d39' User entered 'No (N)'	System	05 Feb 2021 05:06:02
	System	05 Feb 2021 05:06:02

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-05T00:05:56', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '21442682-a84c-4cf5-9ad3-49dfff964d39'	System	05 Feb 2021 05:06:02
User entered 'No (N)'	System	05 Feb 2021 05:06:02

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-05T00:05:59', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '21442682-a84c-4cf5-9ad3-49dfff964d39'	System	05 Feb 2021 05:06:02
User entered '05 Feb 2021 00:05:59'	System	05 Feb 2021 05:06:02

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-12T08:14:59', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '401c188a-f5db-4765-9d89-9f578a235321' User entered 'No (N)'	System	12 Feb 2021 13:15:06
	System	12 Feb 2021 13:15:06

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-12T08:15:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '401c188a-f5db-4765-9d89-9f578a235321' User entered 'No (N)'	System	12 Feb 2021 13:15:06

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-12T08:15:04', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '401c188a-f5db-4765-9d89-9f578a235321' User entered '12 Feb 2021 08:15:04'	System	12 Feb 2021 13:15:06
	System	12 Feb 2021 13:15:06

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-19T08:20:17', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7500f349-ddea-4597-bd21-5300ab56975a' User entered 'No (N)'	System	19 Feb 2021 13:20:23
	System	19 Feb 2021 13:20:23

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-19T08:20:12', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7500f349-ddea-4597-bd21-5300ab56975a' User entered 'No (N)'	System	19 Feb 2021 13:20:23
	System	19 Feb 2021 13:20:23

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-19T08:20:20', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7500f349-ddea-4597-bd21-5300ab56975a' User entered '19 Feb 2021 08:20:20'	System	19 Feb 2021 13:20:23
	System	19 Feb 2021 13:20:23

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-27T08:56:57-05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6edf1d36-18bd-4655-a5b5-375429e90a4c' User entered 'No (N)'	System	27 Feb 2021 13:57:09
	System	27 Feb 2021 13:57:09

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-27T08:56:59-05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6edf1d36-18bd-4655-a5b5-375429e90a4c'	System	27 Feb 2021 13:57:09
User entered 'No (N)'	System	27 Feb 2021 13:57:09

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-02-27T08:57:03-05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '6edf1d36-18bd-4655-a5b5-375429e90a4c' User entered '27 Feb 2021 13:57:03'	System	27 Feb 2021 13:57:09
	System	27 Feb 2021 13:57:09

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-05T05:32:56-05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '51babad0-cef2-4ec6-bf13-c6b593fe55f3'	System	05 Mar 2021 10:33:05
User entered 'No (N)'	System	05 Mar 2021 10:33:05

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-05T05:32:58-05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '51babad0-cef2-4ec6-bf13-c6b593fe55f3'	System	05 Mar 2021 10:33:05
User entered 'No (N)'	System	05 Mar 2021 10:33:05

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-05T05:33:00-05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '51babad0-cef2-4ec6-bf13-c6b593fe55f3' User entered '05 Mar 2021 05:33:00'	System	05 Mar 2021 10:33:05
	System	05 Mar 2021 10:33:05

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-12T01:16:09-05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '15977cae-ab95-4c11-b597-755f8ae0a772'	System	12 Mar 2021 06:16:21
User entered 'No (N)'	System	12 Mar 2021 06:16:21

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-12T01:16:11-05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '15977cae-ab95-4c11-b597-755f8ae0a772'	System	12 Mar 2021 06:16:21
User entered 'No (N)'	System	12 Mar 2021 06:16:21

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-12T01:16:15-05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '15977cae-ab95-4c11-b597-755f8ae0a772'	System	12 Mar 2021 06:16:21
User entered '12 Mar 2021 01:16:15'	System	12 Mar 2021 06:16:21

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-19T07:38:58-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fabd3734-6df8-4945-b0c2-a72ae2eb40e2'	System	19 Mar 2021 11:39:08
User entered 'No (N)'	System	19 Mar 2021 11:39:08

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-19T07:39:00-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fabd3734-6df8-4945-b0c2-a72ae2eb40e2'	System	19 Mar 2021 11:39:08
User entered 'No (N)'	System	19 Mar 2021 11:39:08

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-19T07:39:03-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fabd3734-6df8-4945-b0c2-a72ae2eb40e2'	System	19 Mar 2021 11:39:08
User entered '19 Mar 2021 07:39:03'	System	19 Mar 2021 11:39:08

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-26T13:01:13-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '31dc83bf-8a83-40c6-ba58-9240a893d02f'	System	28 Mar 2021 10:33:46
User entered 'No (N)'	System	28 Mar 2021 10:33:46

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-26T13:01:16-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '31dc83bf-8a83-40c6-ba58-9240a893d02f' User entered 'No (N)'	System	28 Mar 2021 10:33:46

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-26T13:01:19-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '31dc83bf-8a83-40c6-ba58-9240a893d02f' User entered '26 Mar 2021 13:01:19'	System	28 Mar 2021 10:33:46
	System	28 Mar 2021 10:33:46

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-02T03:50:04-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '9749040b-7351-4840-a6f7-c3a75f659be3' User entered 'No (N)'	System	02 Apr 2021 07:50:13
	System	02 Apr 2021 07:50:13

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-02T03:49:56-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '9749040b-7351-4840-a6f7-c3a75f659be3'	System	02 Apr 2021 07:50:13
User entered 'No (N)'	System	02 Apr 2021 07:50:13

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-02T03:50:10-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '9749040b-7351-4840-a6f7-c3a75f659be3'	System	02 Apr 2021 07:50:13
User entered '02 Apr 2021 03:50:10'	System	02 Apr 2021 07:50:13

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-09T00:52:44-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7ca53808-53bb-4967-a106-332468bd79dd'	System	09 Apr 2021 04:52:53
User entered 'No (N)'	System	09 Apr 2021 04:52:53

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-09T00:52:47-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7ca53808-53bb-4967-a106-332468bd79dd'	System	09 Apr 2021 04:52:53
User entered 'No (N)'	System	09 Apr 2021 04:52:53

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-09T00:52:51-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '7ca53808-53bb-4967-a106-332468bd79dd'	System	09 Apr 2021 04:52:53
User entered '09 Apr 2021 00:52:51'	System	09 Apr 2021 04:52:53

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-17T11:46:03-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'b4f104f9-e8e4-4828-91d4-1f6fb23863ff' User entered 'No (N)'	System	17 Apr 2021 15:46:12

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-17T11:46:05-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'b4f104f9-e8e4-4828-91d4-1f6fb23863ff' User entered 'No (N)'	System	17 Apr 2021 15:46:12

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-17T11:46:08-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'b4f104f9-e8e4-4828-91d4-1f6fb23863ff' User entered '17 Apr 2021 11:46:08'	System	17 Apr 2021 15:46:12
	System	17 Apr 2021 15:46:12

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-23T07:00:25-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f90b1912-5d8b-4e8a-a6cd-cfda965866f1' User entered 'No (N)'	System	23 Apr 2021 11:00:38
	System	23 Apr 2021 11:00:38

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-23T07:00:27-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f90b1912-5d8b-4e8a-a6cd-cfda965866f1'	System	23 Apr 2021 11:00:38
User entered 'No (N)'	System	23 Apr 2021 11:00:38

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-23T07:00:33-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'f90b1912-5d8b-4e8a-a6cd-cfda965866f1'	System	23 Apr 2021 11:00:38
User entered '23 Apr 2021 07:00:33'	System	23 Apr 2021 11:00:38

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-30T09:54:11-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fe12449d-bafd-4b5a-9222-3fa7414ab589'	System	30 Apr 2021 13:54:21
User entered 'No (N)'	System	30 Apr 2021 13:54:21

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

Have you been exposed to someone with 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 (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-30T09:54:13-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fe12449d-bafd-4b5a-9222-3fa7414ab589'	System	30 Apr 2021 13:54:21
User entered 'No (N)'	System	30 Apr 2021 13:54:21

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-04-30T09:54:17-04:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: 'fe12449d-bafd-4b5a-9222-3fa7414ab589'	System	30 Apr 2021 13:54:21
User entered '30 Apr 2021 09:54:17'	System	30 Apr 2021 13:54:21

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 02:48:36

US3412016

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:26:23

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:48:36
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 02:48:36

US3412016

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:26:23

Have you ever received facial cosmetic injections, such as Juvederm, Voluma, Radiesse, Restylane, Botox or other?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:28:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-01T16:50:48-05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '79ddb8c4-2e1e-49b2-b300-b0a40f693b2f' User entered 'No (N)'	System	03 Mar 2021 23:49:15
	System	03 Mar 2021 23:49:15

US3412016

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:26:23

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:28:30
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (2A150C18-95BB-48E1-BB90-808BA1B20F9A)', Time: '2021-03-01T16:50:52-05:00', User OID: 'PatientReportedOutcome (US3412016)', ODM File OID: '79ddb8c4-2e1e-49b2-b300-b0a40f693b2f' User entered '01 Mar 2021 16:50:52'	System	03 Mar 2021 23:49:15
	System	03 Mar 2021 23:49:15

US3412016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:02
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Oct 2020 19:44:21

US3412016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:02
User entered '22 Oct 2020'	Mason Urban (b) (4)	22 Oct 2020 19:44:21

US3412016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:02
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	22 Oct 2020 19:44:21

US3412016

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:02
User entered empty.	Mason Urban (b) (4)	22 Oct 2020 19:44:21

US3412016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:26:02
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Oct 2020 19:44:28

US3412016

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:57
User entered 'I'	System	22 Oct 2020 19:44:28

US3412016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:35:54
User entered 'Yes (Y)'		25 Nov 2020 18:57:35

US3412016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:35:54
User entered '25 Nov 2020'		25 Nov 2020 18:57:35

US3412016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:35:54
User entered 'Contact Made (CONTACT MADE)'		25 Nov 2020 18:57:35

US3412016

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 20:35:54
User entered empty.		25 Nov 2020 18:57:35

US3412016

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:35:58
User closed query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 18:58:10
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	25 Nov 2020 18:58:10
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	25 Nov 2020 18:58:10
User opened query 'Data is required. Please complete.' (Site from System).	System	25 Nov 2020 18:57:41
User entered empty.	(b) (4), (b) (6)	25 Nov 2020 18:57:41

US3412016

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User entered '1'	System	25 Nov 2020 18:58:10
User entered empty.	System	25 Nov 2020 18:57:41

US3412016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Dec 2020 17:33:01

US3412016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '23 Dec 2020'	Mason Urban (b) (4)	23 Dec 2020 17:33:01

US3412016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	23 Dec 2020 17:33:01

US3412016

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	Mason Urban (b) (4)	23 Dec 2020 17:33:01

US3412016

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	23 Dec 2020 17:33:06

US3412016

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User entered 'I'	System	23 Dec 2020 17:33:06

US3412016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 17:18:25

US3412016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit. ' (Site from DM). User signature succeeded.	(b) (4)	12 Apr 2021 10:14:46
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit. ' answered with 'visit 4 was on 19FEB2021' (Site from DM).	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 19MAR2021 is recorded under Visit 04 Day 209 visit in PPD Central Lab, however the same is missing in EDC. Please review and update the sample data in EDC under appropriate Visit. ' (Site from DM). User entered '22 Jan 2021'	(b) (4), (b) (6)	01 Apr 2021 18:38:09
	(b) (4)	29 Mar 2021 12:00:14
	Mason Urban (b) (4)	22 Jan 2021 17:18:25
	(b) (4)	

US3412016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	22 Jan 2021 17:18:25

US3412016

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	Mason Urban (b) (4)	22 Jan 2021 17:18:25

US3412016

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Jan 2021 17:18:33

US3412016

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User entered 'I'	System	22 Jan 2021 17:18:33

US3412016

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:32

US3412016

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:32

US3412016

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:32

US3412016

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User entered 'VISIT4'	System	29 Mar 2021 19:19:32

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
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	29 Mar 2021 19:49:38
User entered 'No (N)' reason for change: Data Entry Error	System	29 Mar 2021 19:49:38
User opened query 'Data is required. Please complete.' (Site from System).	Andrea Newlands (b) (4)	29 Mar 2021 19:49:31
User entered empty; reason for change Data Entry Error	(b) (4)	
User entered 'No (N)'	(b) (4), (b) (6)	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User entered empty.	System	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User entered empty.	System	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User entered empty.	System	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User entered empty.	System	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User entered empty.	System	29 Mar 2021 19:19:54

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49

US3412016

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:26:23

[Weight \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49

US3412016

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:23

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:17

US3412016

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:26:23

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:17

US3412016

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:49

US3412016

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '19 Feb 2021'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:49

US3412016

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '11:06'	(b) (4) (b) (4), (b) (6)	29 Mar 2021 19:20:49

US3412016

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User entered '19 Feb 2021 11:06'	System	29 Mar 2021 19:20:49

US3412016

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Mar 2021 17:56:23

US3412016

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:49
User entered 'I'	System	22 Mar 2021 17:56:23

US3412016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Mar 2021 17:56:41

US3412016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '22 Mar 2021'	Mason Urban (b) (4)	22 Mar 2021 17:56:41

US3412016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4)	22 Mar 2021 17:56:41

US3412016

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	Mason Urban (b) (4)	22 Mar 2021 17:56:41

US3412016

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	22 Mar 2021 17:56:44

US3412016

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User entered 'I'	System	22 Mar 2021 17:56:44

US3412016

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:45:37

US3412016

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:14
User entered '20 Apr 2021'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:45:37

US3412016

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:14
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:45:37

US3412016

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:26:23

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:14
User entered empty.	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:45:37

US3412016

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:14
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:45:40

US3412016

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:26:23

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	20 Apr 2021 14:45:40

US3412016

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

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Jan 2021 20:19:22

US3412016

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

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '11 Jan 2021'	Mason Urban (b) (4)	11 Jan 2021 20:19:22

US3412016

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

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Clinic (Clinic)'	Mason Urban (b) (4)	11 Jan 2021 20:19:22

US3412016

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

Form: Visit Date

Generated On: 09 Jun 2021 17:26:23

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User entered 'UNBLND_DECIDE'	System	11 Jan 2021 20:19:22

US3412016

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:23

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '11 Jan 2021'	Mason Urban (b) (4)	11 Jan 2021 20:19:38

US3412016

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:23

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:46:29

US3412016

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:23

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Jan 2021 20:19:38

US3412016

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:23

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:00
User closed query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Apr 2021 08:40:31
Query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 18:00:10
Signature has been broken.	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 18:00:07
User entered 'Amendment 6 or later (Amendment 6 or later)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 18:00:07
User opened query 'Per IRT system use and date, this subject was unblinded when the site was approved for A6. Subject was unblinded under A6, please review and update blank field.' (Site from DM).	(b) (4), (b) (6)	08 Apr 2021 17:39:04
User signature succeeded.	Richard Powell (b) (4) (b) (4)	05 Apr 2021 14:58:13
User entered empty. WR# 5295537	System	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:46:29

US3412016

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:23

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '11 Jan 2021'	Mason Urban (b) (4)	11 Jan 2021 20:19:38

US3412016

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:23

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	11 Jan 2021 20:19:38

US3412016

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:23

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:07:01
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	11 Jan 2021 20:19:38
	(b) (4)	

US3412016

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:23

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Amendment Manager: User entered 'mRNA-1273 (mRNA-1273)'	(b) (4)	20 Jan 2021 11:07:01
User entered 'mRNA-1273 (mRNA-1273)'	Mason Urban (b) (4)	11 Jan 2021 20:19:38
	(b) (4)	

US3412016

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:23

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'No (N)'	Mason Urban (b) (4)	11 Jan 2021 20:19:38

US3412016

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:23

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User entered empty.	System	11 Jan 2021 20:19:38

US3412016

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

Form: Unblinding

Generated On: 09 Jun 2021 17:26:23

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User entered empty.	System	11 Jan 2021 20:19:38

US3412016

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Jan 2021 20:19:48

US3412016

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '11 Jan 2021'	Mason Urban (b) (4)	11 Jan 2021 20:19:48

US3412016

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '10:43'	Mason Urban (b) (4)	11 Jan 2021 20:19:48

US3412016

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User entered '11 Jan 2021 10:43'	System	11 Jan 2021 20:19:48

US3412016

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:23

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)'	Mason Urban (b) (4)	11 Jan 2021 20:19:58

US3412016

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:23

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '11 Jan 2021'	Mason Urban (b) (4)	11 Jan 2021 20:19:58

US3412016

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:23

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '10:46'	Mason Urban (b) (4)	11 Jan 2021 20:19:58

US3412016

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:25
User entered '11 Jan 2021 10:46'	System	11 Jan 2021 20:19:58

US3412016

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:26:23

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:20
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:25:04
User entered 'Yes (Y)'	Steven Anderson (b) (4)	15 Dec 2020 16:56:53

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User closed query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:18:05
Query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' answered with 'Subject saw PCP for this issue. Illness visit not required' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 18:31:36
User opened query 'Per MM, the AE term is a symptom of COVID-19. Please review and confirm if the subject was arranged for an illness visit within 72 hours (but not more than 14 days) to collect an NP swab sample for testing for SARS-CoV-2 infection. If no, please ensure a protocol deviation is captured (as appropriate).' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 09:06:45
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLG: Respiratory disorders NEC, HLT: Breathing abnormalities, PT: Dyspnoea, LLT: Shortness of breath - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 17:54:34
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	09 Feb 2021 17:54:34
Data point term sent to Coder	System	09 Feb 2021 17:53:48
User entered 'SOB'	Melissa Fuson (b) (4) (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'No (N)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered '15 Dec 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	09 Apr 2021 16:58:34
	(b) (4)	
User entered '15 Jan 2021'	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' canceled (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:54:13
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).		01 Mar 2021 07:54:04
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Not Related (NOT RELATED)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Not Related (NOT RELATED)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered 'None (NONE)'	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 17:11:16
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:11:34
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered 'l'	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per CDM RQ: Response noted. However, corresponding ConProc appears to occur prior to AE start date. Please clarify or update as appropriate.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	13 Apr 2021 10:53:46
Query 'Per CDM RQ: Response noted. However, corresponding ConProc appears to occur prior to AE start date. Please clarify or update as appropriate.' answered with 'the date was incorrectly put into this. SOB date was 15-dec-20 and has been updated accordingly' (Site from DM).	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User opened query 'Per CDM RQ: Response noted. However, corresponding ConProc appears to occur prior to AE start date. Please clarify or update as appropriate.' (Site from DM).	(b) (4)	
User closed query 'Per DM: ConProc is checked on AE of SOB; however, there is no matching indication given on ConProc eCRF. Please review and update as appropriate.' (Site from DM).	Steven Anderson (b) (4)	09 Apr 2021 16:59:15
Query 'Per DM: ConProc is checked on AE of SOB; however, there is no matching indication given on ConProc eCRF. Please review and update as appropriate.' answered with 'information has been updated' (Site from DM).	(b) (4)	
User opened query 'Per DM: ConProc is checked on AE of SOB; however, there is no matching indication given on ConProc eCRF. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:19:50
User closed query 'Per DM: ConProc is checked on AE of SOB; however, there is no matching indication given on ConProc eCRF. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:19:50
Query 'Per DM: ConProc is checked on AE of SOB; however, there is no matching indication given on ConProc eCRF. Please review and update as appropriate.' answered with 'information has been updated' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 18:32:42
User opened query 'Per DM: ConProc is checked on AE of SOB; however, there is no matching indication given on ConProc eCRF. Please review and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Feb 2021 05:30:27
User entered 'I'	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Unknown (UNKNOWN)'	(b) (4) Melissa Fuson (b) (4)	09 Feb 2021 17:53:26

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 17:53:26
	(b) (4)	

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:26:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Feb 2021 17:53:26

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User coded data point as SOC: Respiratory, thoracic and mediastinal disorders, HLGT: Upper respiratory tract disorders (excl infections), HLT: Laryngeal spasm, oedema and obstruction, PT: Laryngeal oedema, LLT: Vocal cord edema - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4)	24 Feb 2021 16:11:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Feb 2021 16:11:00
Data point term sent to Coder	System	19 Feb 2021 22:44:14
User entered 'vocal cord swelling'	(b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

Start time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User closed query 'Start time is present for an AE thatSystem did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	19 Feb 2021 22:44:09
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Feb 2021 22:44:09
User entered empty; reason for change Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 22:44:09
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Feb 2021 22:43:43
User opened query 'Start time is present for an AE that did not start within 24 hours after dosing. Please remove the Start time.' (Site from System).	System	19 Feb 2021 22:43:43
User entered 'UN:UN' (non-conformant).	(b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 22:44:09
User entered '4 Dec 2020 UN:UN' (non-conformant).	System	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:20:07
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' answered with 'at this time this AE is still ongoing.' (Site from DM).		01 Apr 2021 18:40:40
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing.' (Site from DM).		01 Mar 2021 07:54:27
User entered 'Yes (Y)'		19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Not Related (NOT RELATED)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered '0'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

Concomitant Medication

Audit	User	Time (GMT)
User closed query 'Per CDM RQ: Response noted. However, there is no ConMed recorded with indication that matches the AE of VOCAL CORD SWELLING. Please update, else clarify. ' (Site from DM).	(b) (4), (b) (6)	13 Apr 2021 10:57:32
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
Query 'Per CDM RQ: Response noted. However, there is no ConMed recorded with indication that matches the AE of VOCAL CORD SWELLING. Please update, else clarify. ' answered with 'this was incorrectly mark subject had a procedure done and no medications added for this ae ' (Site from DM).	Steven Anderson (b) (4)	09 Apr 2021 18:17:37
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	09 Apr 2021 18:10:15
User opened query 'Per CDM RQ: Response noted. However, there is no ConMed recorded with indication that matches the AE of VOCAL CORD SWELLING. Please update, else clarify. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:21:50
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:20:13
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'information has been updated' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 18:41:22

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM). User entered 'I'	(b) (4), (b) (6)	01 Mar 2021 07:54:40
		19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	09 Apr 2021 18:10:15
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered empty.	(b) (4) (b) (4), (b) (6)	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:26:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Feb 2021 22:43:43

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:38:26
Reviewed for Safety.		22 Feb 2021 17:22:38
User entered 'USA-US061-2020-mRNA-1273-P301000018'		22 Feb 2021 17:22:31

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Adverse event](#)

Audit	User	Time (GMT)
User opened query 'IQVIA Medical query: Please consider updating the event term to the cause of acute chest pain if final diagnosis is known.' (Site from Safety).	(b) (4), (b) (6)	01 May 2021 16:28:38
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 12:10:42
User closed query 'No MI per hospital records? Consider updating to Acute Chest pain (cardiac)? Please review medical records and update accordingly' (Site from CRA).	(b) (4), (b) (6)	06 Apr 2021 12:10:30
User coded data point as SOC: General disorders and administration site conditions, HLGT: General system disorders NEC, HLT: Pain and discomfort NEC, PT: Chest pain, LLT: Acute chest pain - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 18:24:12
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	01 Apr 2021 18:24:12
Data point term sent to Coder	System	01 Apr 2021 18:22:15
Query 'No MI per hospital records? Consider updating to Acute Chest pain (cardiac)? Please review medical records and update accordingly' answered with 'information has been updated' (Site from CRA).	(b) (4), (b) (6)	01 Apr 2021 18:21:35
Coding entries removed.	(b) (4), (b) (6)	01 Apr 2021 18:21:19
User entered 'Acute chest pain' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 18:21:19
User opened query 'No MI per hospital records? Consider updating to Acute Chest pain (cardiac)? Please review medical records and update accordingly' (Site from CRA).	(b) (4), (b) (6)	25 Mar 2021 16:38:37
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Myocardial infarction, LLT: Myocardial infarction - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 23:19:00
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 23:19:00
Data point term sent to Coder	System	19 Feb 2021 23:18:49

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Adverse event](#)

Audit	User	Time (GMT)
User entered 'Myocardial Infarction'	(b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:38:39
User entered 'Yes (Y)'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:38:41
User entered 'No (N)'	(b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:38:44
User entered 'No (N)'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 23:31:18
User entered '2 Dec 2020'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 23:31:20
User entered empty.		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:39:01
User entered 'No (N)'	(b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:24:02
User closed query 'Please confirm stop date - still present at discharge on 04 Dec 2020' (Site from CRA).		15 Apr 2021 12:24:00
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User closed query 'PV Query: End date for the myocardial infarction on 02 Dec 2020 was provided as 03 Dec 2020 but the subject remained hospitalized until 04 Dec 2020. Please consider revising end date for this event.' (Site from Safety).	(b) (4), (b) (6)	02 Apr 2021 17:23:52
Query 'Please confirm stop date - still present at discharge on 04 Dec 2020' answered with 'information has been updated' (Site from CRA).		01 Apr 2021 18:22:41
Query 'PV Query: End date for the myocardial infarction on 02 Dec 2020 was provided as 03 Dec 2020 but the subject remained hospitalized until 04 Dec 2020. Please consider revising end date for this event.' answered with 'information has been updated' (Site from Safety).		01 Apr 2021 18:22:38
User entered '4 Dec 2020' reason for change: Data Entry Error		01 Apr 2021 18:22:32
User opened query 'Please confirm stop date - still present at discharge on 04 Dec 2020' (Site from CRA).		25 Mar 2021 16:42:06
User opened query 'PV Query: End date for the myocardial infarction on 02 Dec 2020 was provided as 03 Dec 2020 but the subject remained hospitalized until 04 Dec 2020. Please consider revising end date for this event.' (Site from Safety).		27 Feb 2021 18:46:48
User entered '03 Dec 2020'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

End time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 12:10:56
User entered empty.		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:42:35
User entered 'Grade 4 (Grade 4)'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 16:42:49
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Feb 2021 23:18:57
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Feb 2021 23:17:58
User entered 'Yes (Y)'	(b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4)	25 Mar 2021 16:43:33
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:43:34
User entered '0'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:43:36
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	19 Feb 2021 23:18:57
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).	System	19 Feb 2021 23:18:57
User entered '1' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 23:18:57
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	System	19 Feb 2021 23:17:58
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:43:38
User entered '2 Dec 2020'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:43:42
User entered '4 Dec 2020'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4)	25 Mar 2021 16:43:55
User entered 'No (N)'	(b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:43:57
User entered empty.		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4)	25 Mar 2021 16:43:59
User entered '0'	(b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:44:04
User entered '0'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:44:08
User entered '0'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User opened query 'IQVIA Medical query: Since the subject received both doses of study drug before this event started, the relationship to investigational product and study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	01 May 2021 16:27:09
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 16:44:41
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 23:18:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 23:18:57
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 23:18:57
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 23:17:58
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User opened query 'IQVIA Medical query: Since the subject received both doses of study drug before this event started, the relationship to investigational product and study procedure must be reported as "Related" or "Not Related". Please update the CRF accordingly. ' (Site from Safety).	(b) (4), (b) (6)	01 May 2021 16:27:22
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 16:44:43
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 23:18:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 23:18:57
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	(b) (4), (b) (6)	19 Feb 2021 23:18:57
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 23:17:58
User entered empty.	(b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:44:45
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:44:50
User entered '0'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:24:25
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User closed query 'Please add all Con Meds during hospitalization' (Site from CRA).	(b) (4), (b) (6)	07 Apr 2021 19:48:26
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		05 Apr 2021 13:22:07
Query 'Please add all Con Meds during hospitalization' answered with 'information has been updated' (Site from CRA).		01 Apr 2021 18:22:57
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'information has been updated' (Site from DM).		01 Apr 2021 18:22:55
User opened query 'Please add all Con Meds during hospitalization' (Site from CRA).		25 Mar 2021 16:46:06
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		01 Mar 2021 07:55:19
User entered 'I'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:45:03
User entered '0'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:24:30
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	(b) (4) (b) (4), (b) (6)	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:45:08
User entered empty.		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:08:32
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:45:36
User entered 'Previous SAE USA-US061-2020-MRNA-1273P301000018 of MI is being revised due to receipt of the subjects medical records. Medical records state chest pain mid substernal without radiation woke him from his sleep @ 01:00 on 12/2/2020. Subject went to the ER department, was evaluated, a cardiac cath was performed and placement of 2 stents were completed. Subject was discharged from the hospital on 12/4/2020.'		19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Feb 2021 23:17:58

US3412016

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:26:23

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	19 Feb 2021 23:17:58

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:26:23

[Were any prior/concomitant medications and/or vaccinations taken?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	13 Aug 2020 15:39:42
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 20:16:05

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: ASPIRIN [ACETYLSALICYLIC ACID] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 23:19:11
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 23:19:11
Data point term sent to Coder	System	13 Aug 2020 15:41:04
User entered 'ASPIRIN'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 15:40:37

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 17:41:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Aug 2020 17:41:32
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:41:32
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 15:40:37
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 15:40:37

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'HEART ATTACK'	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '81'	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:06
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	13 Aug 2020 15:40:37
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 15:40:37

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 15:40:37
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:40:37

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:40:37

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:40:37

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN, PRODUCTSYNONYM: LIPITOR [ATORVASTATIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 15:44:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 15:44:22
Data point term sent to Coder	System	13 Aug 2020 15:43:09
User entered 'LIPITOR'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 15:42:09

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'HYPERLIPIDEMIA'	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '80'	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:10
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	13 Aug 2020 15:42:09
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 15:42:09

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 15:42:09
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:42:09

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:42:09

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:42:09

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SODIUM-GLUCOSE CO-TRANSPORTER 2 (SGLT2) INHIBITORS, PRODUCT: EMPAGLIFLOZIN, PRODUCTSYNONYM: JARDIANCE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 15:45:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Aug 2020 15:45:24
Data point term sent to Coder	System	13 Aug 2020 15:44:10
User entered 'JARDIANCE'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 15:43:15

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'DM2'	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '25'	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:13
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	13 Aug 2020 15:43:15
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 15:43:15

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 15:43:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:43:15

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 15:43:15

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 15:43:15

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: FIBRATES, PRODUCT: FENOFIBRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 16:44:26
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:44:26
Data point term sent to Coder	System	13 Aug 2020 16:43:29
User entered 'FENOFIBRATE'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:43:13

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'HYPERLIPIDEMIA'	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '145'	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:17
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	13 Aug 2020 16:43:13
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:43:13

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:43:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:43:13

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:43:13

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 16:43:13

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
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 HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 20:53:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 20:53:42
Data point term sent to Coder Coding entries removed.	System Mylene Asmar-Rios (b) (4)	29 Sep 2020 20:52:52 29 Sep 2020 20:51:59
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 HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:22:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 17:22:38
Data point term sent to Coder Coding entries removed.	System Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:15:17 29 Sep 2020 17:14:26
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 HYDROCHLORIDE, PRODUCTSYNONYM: FLEXERIL [CYCLOBENZAPRINE HYDROCHLORIDE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Aug 2020 00:26:11

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003. Data point term sent to Coder User entered 'FLEXERIL'	Coder Import (b) (4) (b) (4) System Mylene Asmar-Rios (b) (4)	14 Aug 2020 00:26:11 13 Aug 2020 16:47:45 13 Aug 2020 16:47:36

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per DM CLR: Please update the indication to reflect the location and type (e.g. Sensory or Motor) of NEUROPATHY. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:42:54
User entered 'BACK PAIN' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	29 Sep 2020 20:51:59
Query 'Per DM CLR: Please update the indication to reflect the location and type (e.g. Sensory or Motor) of NEUROPATHY. Please reconcile with Med History eCRF as appropriate. ' answered with 'unknown ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:14:42
User entered 'diabetic NEUROPATHY' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:14:26
User opened query 'Per DM CLR: Please update the indication to reflect the location and type (e.g. Sensory or Motor) of NEUROPATHY. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:26:27
User entered 'NEUROPATHY'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:47:36

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '5'	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	27 Nov 2020 04:12:48
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' answered with 'MH condition date confirmed and updated' (Site from DM).	Mylene Asmar-Rios (b) (4)	20 Nov 2020 15:45:29
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:53:38
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		15 Aug 2020 12:45:20
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	13 Aug 2020 16:47:36
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:47:36

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:47:36
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:47:36

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:47:36

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 16:47:36

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 16:51:24
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:51:24
Data point term sent to Coder	System	13 Aug 2020 16:49:48
User entered 'GABAPENTIN'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:49:13

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per DM CLR: Please update the indication to reflect the location and type (e.g. Sensory or Motor) of DIABETIC NEUROPATHY. Please reconcile with Med History eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:43:08
Query 'Per DM CLR: Please update the indication to reflect the location and type (e.g. Sensory or Motor) of DIABETIC NEUROPATHY. Please reconcile with Med History eCRF as appropriate.' answered with 'unknown ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:15:54
User opened query 'Per DM CLR: Please update the indication to reflect the location and type (e.g. Sensory or Motor) of DIABETIC NEUROPATHY. Please reconcile with Med History eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:27:09
User entered 'DIABETIC NEUROPATHY'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:49:13

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '400'	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'three times daily (TID)'	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2018). Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:14:06
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2018). Please review and reconcile Con Med and Med History start dates as appropriate.' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:18:12
User entered 'UN UNK 2018' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:18:02
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2018). Please review and reconcile Con Med and Med History start dates as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:26:53
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).		15 Aug 2020 12:45:24
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	13 Aug 2020 16:49:13
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:49:13

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:49:13
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Aug 2020 16:49:13

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:49:13

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 16:49:13

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
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 LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	30 Sep 2020 03:24:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 03:24:47
Data point term sent to Coder	System	29 Sep 2020 17:19:30
Coding entries removed.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:19:19
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 LISPRO, PRODUCTSYNONYM: HUMALOG - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 11:29:13
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 11:29:13
Data point term sent to Coder	System	13 Aug 2020 16:50:50
User entered 'HUMALOG'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:50:46

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:50:46
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'DM2'	Mylene Asmar-Rios	13 Aug 2020 16:50:46
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '100'	Mylene Asmar-Rios	13 Aug 2020 16:50:46
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:13:35
Query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' answered with 'updated.' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:19:34
User entered 'Other (OTHER)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:19:19
User opened query 'Per DM CLR: Please review the unit for this medication as this is not the expected unit for this medication or the dosage. Please correct the unit as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:27:28
User entered 'mL (mL)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:50:46

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'units/mL' reason for change: Data Entry Error	Jacob sekinger (b) (4)	29 Sep 2020 17:19:19
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:50:46
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	13 Aug 2020 16:50:46
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:50:46
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Sep 2020 19:13:47
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:19:28
User entered 'Subcutaneous (SUBCUTANEOUS)' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:19:19
User opened query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:27:38
User entered 'Intramuscular (INTRAMUSCULAR)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:50:46

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:50:46
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:27
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	13 Aug 2020 16:50:46
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:50:46

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 16:50:46
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 16:50:46
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:50:46
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:50:46
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:50:46

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:50:46

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 16:50:46

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE DINITRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 10:52:15
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 10:52:15
Data point term sent to Coder	System	13 Aug 2020 16:53:56
User entered 'ISOSORBIDE DINITRATE'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	13 Aug 2020 16:53:14
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'HEART ATTACK'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '10'	(b) (4) Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'mg (mg)'	(b) (4) Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) Mylene Asmar-Rios	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios	13 Aug 2020 16:53:14
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) Mylene Asmar-Rios	13 Aug 2020 16:53:14
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'Oral (ORAL)'	(b) (4) Mylene Asmar-Rios	13 Aug 2020 16:53:14
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) Mylene Asmar-Rios	13 Aug 2020 16:53:14
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:32
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	13 Aug 2020 16:53:14
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '0'	(b) (4) Mylene Asmar-Rios	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:24:10
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:36:42
User entered '3 Dec 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 18:36:42
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '4 Dec 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 18:24:10
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User entered '1'	System	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User entered '1'	System	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:49
User entered '804 (804)'	System	13 Aug 2020 16:53:14

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
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)	13 Aug 2020 16:56:31
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:56:31
Data point term sent to Coder	System	13 Aug 2020 16:54:59
User entered 'LISINOPRIL'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:54:22

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'HYPERTENSION'	(b) (4) Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:54:22

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '5'	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:35
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	13 Aug 2020 16:54:22
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:54:22

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:54:22
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:54:22

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:54:22

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 16:54:22

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
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 Nov 2020 09:19:10
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	23 Nov 2020 09:19:10
Data point term sent to Coder	System	20 Nov 2020 16:02:54
Coding entries removed.	Mylene Asmar-Rios (b) (4)	20 Nov 2020 16:02:50
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.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:32:38
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	30 Sep 2020 00:32:38
Data point term sent to Coder	System	29 Sep 2020 17:23:47
Coding entries removed.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:23:27
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.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:58:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 16:58:22
Data point term sent to Coder	System	13 Aug 2020 16:57:02
User entered 'LORATADINE'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:56:55

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
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)	27 Nov 2020 04:12:58
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 'MH confirm and updated ' (Site from DM).	Mylene Asmar-Rios (b) (4)	20 Nov 2020 16:03:04
User entered 'ALLERGIC - SEASONAL' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	20 Nov 2020 16:02:50
User opened query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF. ' (Site from DM).	(b) (4), (b) (6)	18 Nov 2020 19:53:23
User closed query 'Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).		12 Oct 2020 17:44:21
Query 'Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with Med History eCRF as appropriate. ' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:23:34
User entered 'ALLERGIES - seasonal' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 17:23:27
User opened query 'Per DM CLR: Please update the indication to reflect the location/type of ALLERGIES. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:28:07
User entered 'ALLERGIES'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:56:55

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '10'	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:39
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	13 Aug 2020 16:56:55
User entered 'UN UNK 2012'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:56:55

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:56:55
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:56:55

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:56:55

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 16:56:55

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: BIGUANIDES, PRODUCT: METFORMIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	14 Aug 2020 07:23:18
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 07:23:18
Data point term sent to Coder	System	13 Aug 2020 16:59:05
User entered 'METFORMIN'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:58:06

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'DM2'	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '500'	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'three times daily (TID)'	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:42
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	13 Aug 2020 16:58:06
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 16:58:06

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 16:58:06
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	13 Aug 2020 16:58:06

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 16:58:06

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 16:58:06

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 17:04:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 17:04:28
Data point term sent to Coder	System	13 Aug 2020 17:04:16
User entered 'METOPROLOL'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:03:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'HYPERTENSION'	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '50'	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'twice daily (BID)'	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:46
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	13 Aug 2020 17:03:32
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:03:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 17:03:32
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Aug 2020 17:03:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:03:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 17:03:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Aug 2020 12:48:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Aug 2020 12:48:14
Data point term sent to Coder	System	13 Aug 2020 17:45:48
User entered 'NITROGLYCERIN'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:45:38

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'HEART ATTACK'	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '4'	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'as needed (PRN)'	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:50
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	13 Aug 2020 17:45:38
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:45:38

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 17:45:38
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 17:45:38

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 17:45:38

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Aug 2020 17:45:38

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: BARBITURATES AND DERIVATIVES, PRODUCT: PRIMIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 20:53:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	29 Sep 2020 20:53:42
Data point term sent to Coder Coding entries removed.	System	29 Sep 2020 20:52:53
	Mylene Asmar-Rios	29 Sep 2020 20:52:25
	(b) (4)	
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: BARBITURATES AND DERIVATIVES, PRODUCT: PRIMIDONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 15:42:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Aug 2020 15:42:21
Data point term sent to Coder	System	13 Aug 2020 17:51:03
User entered 'PRIMIDONE'	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per DM CLR: Please update the indication to reflect the location and type (e.g. Sensory or Motor) of NEUROPATHY. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 17:42:45
Query 'Per DM CLR: Please update the indication to reflect the location and type (e.g. Sensory or Motor) of NEUROPATHY. Please reconcile with Med History eCRF as appropriate. ' answered with 'ESSENTIAL TREMOR ' (Site from DM).	Mylene Asmar-Rios (b) (4)	29 Sep 2020 20:52:35
User entered 'ESSENTIAL TREMOR' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	29 Sep 2020 20:52:25
User opened query 'Per DM CLR: Please update the indication to reflect the location and type (e.g. Sensory or Motor) of NEUROPATHY. Please reconcile with Med History eCRF as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:28:21
User entered 'NEUROPATHY'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:50:20

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '50'	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:45:58
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	13 Aug 2020 17:50:20
User entered 'UN UNK 2019'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:50:20

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:50:20
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	14 Sep 2020 18:19:32
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	14 Sep 2020 18:19:32
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	14 Sep 2020 18:19:32
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Aug 2020 17:50:20
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:50:20

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:50:20

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:50:20

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 17:50:20

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: DIPEPTIDYL PEPTIDASE 4 (DPP-4) INHIBITORS, PRODUCT: SITAGLIPTIN, PRODUCTSYNONYM: JANUVIA [SITAGLIPTIN] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Aug 2020 11:43:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Aug 2020 11:43:27
Data point term sent to Coder	System	13 Aug 2020 17:52:05
User entered 'JANUVIA'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:51:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	13 Aug 2020 17:51:25
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per CDM re-query: Previous response states 'they have been taking this since 2012', however Start Date is recorded as 'UN UNK 2010'. Please review and confirm correct start date and update as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	10 Feb 2021 14:43:50
Query 'Per CDM re-query: Previous response states 'they have been taking this since 2012', however Start Date is recorded as 'UN UNK 2010'. Please review and confirm correct start date and update as appropriate.' answered with 'RESPONSE WAS INCORRECT PER SOURCE HAS BEEN TAKING SINCE 2010' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	09 Feb 2021 18:00:56
User opened query 'Per CDM re-query: Previous response states 'they have been taking this since 2012', however Start Date is recorded as 'UN UNK 2010'. Please review and confirm correct start date and update as appropriate.' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 10:19:28
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HTN; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	09 Feb 2021 10:18:11
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HTN; update Con Med indication or provide clarification. ' answered with 'this was not added for the worseing of a condition. according to subjects medication list they have been taking this since 2012' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Feb 2021 21:20:18
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, consider recording an AE of Worsening HTN; update Con Med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 07:01:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User entered 'DM2'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:51:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '100'	(b) (4) Mylene Asmar-Rios	13 Aug 2020 17:51:25
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'mg (mg)'	(b) (4) Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:51:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) Mylene Asmar-Rios	13 Aug 2020 17:51:25
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'once daily (QD)'	(b) (4) Mylene Asmar-Rios	13 Aug 2020 17:51:25
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) Mylene Asmar-Rios	13 Aug 2020 17:51:25
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'Oral (ORAL)'	(b) (4) Mylene Asmar-Rios	13 Aug 2020 17:51:25
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) Mylene Asmar-Rios	13 Aug 2020 17:51:25
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:46:02
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	13 Aug 2020 17:51:25
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:51:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '0'	(b) (4) Mylene Asmar-Rios	13 Aug 2020 17:51:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per hospital records, this is to be stopped? Please confirm and update as appropriate' (Site from CRA).	(b) (4)	(b) (4), (b) (6) 07 Apr 2021 19:54:12
Query 'Per hospital records, this is to be stopped? Please confirm and update as appropriate' answered with 'information has been updated' (Site from CRA).		01 Apr 2021 18:26:33
User entered 'No (N)' reason for change: Data Entry Error		01 Apr 2021 18:26:27
User opened query 'Per hospital records, this is to be stopped? Please confirm and update as appropriate' (Site from CRA).		25 Mar 2021 15:49:17
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:51:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '4 Dec 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:26:27
User entered empty.	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:51:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'No (N)'	(b) (4) Mylene Asmar-Rios	13 Aug 2020 17:51:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User entered '1'	System	13 Aug 2020 17:51:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User entered '1'	System	13 Aug 2020 17:51:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:50:57
User entered '804 (804)'	System	13 Aug 2020 17:51:25

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OTHER OPIOIDS, PRODUCT: TRAMADOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	13 Aug 2020 17:54:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 17:54:30
Data point term sent to Coder	System	13 Aug 2020 17:53:08
User entered 'TRAMADOL'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:52:17

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'BACK PAIN'	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '50'	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:46:07
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	13 Aug 2020 17:52:17
User entered 'UN UNK 2019'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:52:17

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 17:52:17
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:52:17

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:52:17

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 17:52:17

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: OTHER LIPID MODIFYING AGENTS, PRODUCT: EZETIMIBE, PRODUCTSYNONYM: ZETIA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	13 Aug 2020 17:55:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Aug 2020 17:55:20
Data point term sent to Coder	System	13 Aug 2020 17:54:10
User entered 'ZETIA'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:53:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'HYPERLIPIDEMIA'	(b) (4) Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:53:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '10'	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
Query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	15 Aug 2020 12:46:11
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	13 Aug 2020 17:53:23
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	13 Aug 2020 17:53:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Mylene Asmar-Rios	13 Aug 2020 17:53:23
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:53:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Aug 2020 17:53:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Aug 2020 17:53:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
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)	04 Nov 2020 21:42:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 21:42:30
Data point term sent to Coder	System	04 Nov 2020 21:41:26
User entered 'INFLUENZA VACCINE'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'GENERAL HEALTH'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '0.5'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'mL (mL)'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'once (ONCE)'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'Intramuscular (INTRAMUSCULAR)'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '30 Sep 2020'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '0'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '30 Sep 2020'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'No (N)'	Melissa Fuson (b) (4)	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User entered empty.	System	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User entered empty.	System	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:05
User entered empty.	System	04 Nov 2020 21:40:54

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL TARTRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	18 Dec 2020 09:52:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Dec 2020 09:52:06
Data point term sent to Coder	System	17 Dec 2020 13:23:41
User entered 'METOPROLOLTARTRATE'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 13:23:15

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'HTN'	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '50'	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'three times daily (TID)'	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '09 Dec 2020'	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Dec 2020 13:23:15
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	17 Dec 2020 13:23:15

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 13:23:15

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Dec 2020 13:23:15

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	22 Feb 2021 14:18:58
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Feb 2021 14:18:58
Data point term sent to Coder Coding entries removed.	System Andrea Newlands (b) (4)	22 Feb 2021 14:17:46 22 Feb 2021 14:16:55
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	23 Dec 2020 21:10:17
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 21:10:17
Data point term sent to Coder Coding entries removed.	System Melissa Fuson (b) (4)	23 Dec 2020 19:10:46 23 Dec 2020 19:10:21
User entered 'ZOLPIDEN' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	23 Dec 2020 19:10:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE RELATED DRUGS, PRODUCT: ZOLPIDEM TARTRATE, PRODUCTSYNONYM: ZOPIDEM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Dec 2020 17:35:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Dec 2020 17:35:37
Data point term sent to Coder User entered 'ZDPIDEM'	System Melissa Fuson (b) (4)	17 Dec 2020 13:24:41 17 Dec 2020 13:24:26

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	23 Feb 2021 06:20:26
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:18:22
User entered 'insomnia' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	22 Feb 2021 14:16:55
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition this medication is being used to prevent/treat. Please reconcile with AE or Med History eCRF so there is an appropriate match. Update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 07:01:43
User entered 'SLEEPAIDE'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 13:24:26

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '10'	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'mg (mg)'	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '9 Dec 2020'	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Dec 2020 13:24:26
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 13:24:26

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 13:24:26

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Dec 2020 13:24:26

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: ACETYLSALICYLIC ACID, PRODUCTSYNONYM: BAYER ASPIRIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	17 Dec 2020 17:19:16
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Dec 2020 17:19:16
Data point term sent to Coder	System	17 Dec 2020 13:25:42
User entered 'BAYER ASPIRIN'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 13:25:12

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise. Please review and update as appropriate. Else, provide justification.' (Site from DM).	(b) (4) (b) (4), (b) (6)	09 Feb 2021 10:17:48
Query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise. Please review and update as appropriate. Else, provide justification.' answered with 'this has been updated to indicate as a prophylactic ' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Feb 2021 21:23:24
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Feb 2021 21:23:10
User opened query 'Per DM CLR: The indication signifies prophylaxis. However, the response in this field reflects otherwise. Please review and update as appropriate. Else, provide justification.' (Site from DM).	(b) (4), (b) (6)	22 Jan 2021 07:02:19
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	17 Dec 2020 13:25:12

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'STROKE PREVENTION'	(b) (4) Melissa Fuson (b) (4)	17 Dec 2020 13:25:12

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '81'	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '9 Dec 2020'	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Dec 2020 13:25:12
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 13:25:12

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	17 Dec 2020 13:25:12

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	17 Dec 2020 13:25:12

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: SELECTIVE BETA-2-ADRENORECEPTOR AGONISTS, PRODUCT: SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL [SALBUTAMOL] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 18:08:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 18:08:35
Data point term sent to Coder User entered 'ALBUTEROL'	System	09 Feb 2021 18:07:33
	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'No (N)'	(b) (4)	
	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'SOB'	(b) (4)	
	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '90'	(b) (4)	
	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'ug (ug)' reason for change: Data Entry Error	(b) (4)	08 Apr 2021 21:40:26
User closed query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).	(b) (4)	24 Mar 2021 10:23:31
Query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' answered with 'updated no units for inhaler' (Site from DM).	(b) (4), (b) (6)	23 Mar 2021 19:25:43
User entered 'Other (OTHER)' reason for change: Data Entry Error		23 Mar 2021 19:25:08
User entered 'puff (PUFF)' reason for change: Data Entry Error		23 Mar 2021 19:24:14
User entered 'IU (IU)' reason for change: Data Entry Error		23 Mar 2021 19:24:00
User entered 'g (g)' reason for change: Data Entry Error		23 Mar 2021 19:23:47
User entered 'mL (mL)' reason for change: Data Entry Error		23 Mar 2021 19:23:33
User entered 'ug (ug)' reason for change: Data Entry Error		23 Mar 2021 19:23:18
User opened query 'Per DM CLR: Please review the unit recorded as this is not the expected unit for this medication. Please update the unit as appropriate or provide explanation for alternate unit. ' (Site from DM).		01 Mar 2021 09:12:37
User entered 'mg (mg)'	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
DataPoint activated with code reason code Data required.	(b) (4)	09 Feb 2021 18:05:36
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4)	08 Apr 2021 21:40:26
	(b) (4)	
User entered 'updated 2 puffs as needed' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 19:28:19
User closed query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	23 Mar 2021 19:26:33
User entered 'no units for inhaler' reason for change: Data Entry Error	(b) (4), (b) (6)	23 Mar 2021 19:26:33
User opened query 'Dose unit is Other, however Other, specify is missing. Please provide.' (Site from System).	System	23 Mar 2021 19:25:08
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'as needed (PRN)' reason for change:	Steven Anderson (b) (4)	08 Apr 2021 21:40:26
Data Entry Error	(b) (4)	
User entered 'other (OTHER)'	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
required.	(b) (4)	
DataPoint inactivated with code reason code Data not	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
required.	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User closed query 'Per CDM: As needed is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 12:07:38
Query 'Per CDM: As needed is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' answered with 'this has been updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	08 Apr 2021 21:40:46
User entered empty; reason for change Data Entry Error	Steven Anderson (b) (4) (b) (4)	08 Apr 2021 21:40:26
User opened query 'Per CDM: As needed is an available option in the drop down for frequency. Please consider updating the frequency to the available equivalent rather than Other. Thank you.' (Site from DM).	(b) (4), (b) (6)	02 Apr 2021 17:52:16
User entered '2 PUFFS AS NEEDED'	Melissa Fuson (b) (4) (b) (4)	09 Feb 2021 18:07:24
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4) (b) (4)	09 Feb 2021 18:05:36
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	23 Dec 2020 19:11:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '15 Jan 2021'	(b) (4)	
	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '0'	(b) (4)	
	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'Yes (Y)'	(b) (4)	
	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'No (N)'	(b) (4)	
	Melissa Fuson (b) (4)	09 Feb 2021 18:07:24
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 18:07:24
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 18:07:24
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Feb 2021 18:07:24
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	09 Feb 2021 18:05:36
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	23 Dec 2020 19:11:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 19:11:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 19:11:51
Data point term sent to Coder	System	13 Apr 2021 18:44:43
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 18:43:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Apr 2021 18:43:56
User entered 'vitamin d' reason for change: Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 18:43:56
Data point term sent to Coder	System	13 Apr 2021 18:40:38
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
Data point term sent to Coder	System	13 Apr 2021 18:17:09
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 18:16:33
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:33
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 18:16:33
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), ATC: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD), PRODUCT: OTHER DRUGS FOR PEPTIC ULCER AND GASTRO-OESOPHAGEAL REFLUX DISEASE (GORD) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 18:10:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Feb 2021 18:10:57
Data point term sent to Coder	System	09 Feb 2021 18:09:35
User entered 'GAVISCON'	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 18:43:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 18:43:56
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Apr 2021 18:43:56
User entered 'general health' reason for change: Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 18:43:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 18:16:33
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:33
	(b) (4)	
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 18:16:33
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'GERD'	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered '1250' reason for change: Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 18:43:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '160/105'	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'mg (mg)'	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'other (OTHER)' reason for change:	Andrea Newlands (b) (4)	13 Apr 2021 18:43:56
Data Entry Error	(b) (4)	
DataPoint activated with code reason code Data	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
required.	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
required.	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'as needed (PRN)'	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'twice weekly' reason for change: Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 18:43:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered '04 Dec 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 18:43:56
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '15 Jan 2021'	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered '0'	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered empty.	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
	(b) (4)	
Signature has been broken.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
	(b) (4)	
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
	(b) (4)	
User entered 'No (N)'	Melissa Fuson (b) (4)	09 Feb 2021 18:08:45
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
User entered empty.	System	09 Feb 2021 18:08:45

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
User entered empty.	System	09 Feb 2021 18:08:45

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	13 Apr 2021 18:40:08
DataPoint inactivated with code reason code Data not required.	Andrea Newlands (b) (4)	13 Apr 2021 18:16:42
User entered empty.	System	09 Feb 2021 18:08:45

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: ISOSORBIDE DINITRATE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	06 Apr 2021 12:38:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	06 Apr 2021 12:38:51
Data point term sent to Coder	System	01 Apr 2021 18:25:31
User entered 'Isosorbide Dinitrate'	(b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'Acute chest pain'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '10'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'three times daily (TID)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '4 Dec 2020'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:29:51
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:12:16
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 18:25:30

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
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)	13 Apr 2021 19:12:11
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 19:12:11
Data point term sent to Coder	System	13 Apr 2021 18:50:49
User entered 'novolog'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 18:50:41

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'type 2 diabetes'	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered '100'	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'iu/ml'	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'Subcutaneous (SUBCUTANEOUS)'	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered '04 Dec 2020'	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	13 Apr 2021 18:50:41
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 18:50:41

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 18:50:41

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 18:50:41

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
User coded data point as ATC: SENSORY ORGANS, ATC: OPHTHALMOLOGICALS, ATC: DECONGESTANTS AND ANTIALLERGICS, ATC: OTHER ANTIALLERGICS, PRODUCT: OLOPATADINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	14 Apr 2021 13:01:21
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:01:21
Data point term sent to Coder	System	13 Apr 2021 18:59:59
User entered 'olopatadine 0.7%'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 18:59:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'seasonal allergies'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered '1'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'drop'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'ophthalmic'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'un Mar 2020'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	13 Apr 2021 18:59:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:59:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:59:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	13 Apr 2021 18:59:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 12:30:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: OTHER CARDIAC PREPARATIONS, ATC: OTHER CARDIAC PREPARATIONS, PRODUCT: RANOLAZINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:13:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	14 Apr 2021 09:13:53
Data point term sent to Coder	System	13 Apr 2021 19:07:12
User entered 'ranolazine'	Andrea Newlands (b) (4)	13 Apr 2021 19:06:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:30:17
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:06:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 12:30:20
User entered 'acute chest pain'	Andrea Newlands (b) (4)	13 Apr 2021 19:06:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:30:24
User entered '500'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:06:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:30:27
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:06:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:30:30
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:06:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 12:30:32
User entered 'twice daily (BID)'	Andrea Newlands (b) (4)	13 Apr 2021 19:06:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 12:30:33
User entered empty.	Andrea Newlands (b) (4)	13 Apr 2021 19:06:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 12:30:39
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	13 Apr 2021 19:06:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:30:42
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:06:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:30:48
User entered '04 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:06:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 12:30:51
User entered '0'	Andrea Newlands (b) (4)	13 Apr 2021 19:06:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:30:52
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:06:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:30:57
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:06:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Apr 2021 12:30:59
User entered 'No (N)'	Andrea Newlands (b) (4)	13 Apr 2021 19:06:33
	(b) (4)	

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	13 Apr 2021 19:06:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	13 Apr 2021 19:06:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	13 Apr 2021 19:06:33

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, GENERAL, ATC: OPIOID ANESTHETICS, PRODUCT: FENTANYL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:30:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:30:51
Data point term sent to Coder	System	13 Apr 2021 19:14:32
User entered 'fentanyl'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered 'PCI'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered '50'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered 'ug (ug)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered '0'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:35
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User entered empty.	System	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User entered empty.	System	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:44
User entered empty.	System	13 Apr 2021 19:14:21

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:12:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:12:42
Data point term sent to Coder	System	13 Apr 2021 19:20:37
User entered 'versed'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered 'pci'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered '2'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered '0'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:39
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User entered empty.	System	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User entered empty.	System	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:27
User entered empty.	System	13 Apr 2021 19:20:29

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: MIDAZOLAM HYDROCHLORIDE, PRODUCTSYNONYM: VERSED - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:12:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:12:42
Data point term sent to Coder	System	13 Apr 2021 19:21:38
User entered 'versed'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered 'pci'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered 'l'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered '0'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:44
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User entered empty.	System	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User entered empty.	System	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:17
User entered empty.	System	13 Apr 2021 19:21:00

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:34:57
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:34:57
Data point term sent to Coder	System	13 Apr 2021 19:22:40
User entered 'lidocaine 20mg/ml'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered 'pci'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered 'I'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered 'mL (mL)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered 'Other (OTHER)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered 'injection'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered '0'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:48
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User entered empty.	System	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User entered empty.	System	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:28
User entered empty.	System	13 Apr 2021 19:22:32

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH DIRECT CARDIAC EFFECTS, ATC: PHENYLALKYLAMINE DERIVATIVES, PRODUCT: VERAPAMIL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:12:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 08:12:43
Data point term sent to Coder	System	13 Apr 2021 19:25:48
User entered 'verapamil'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered 'pci'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered '2.5'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered '0'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:52
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User entered empty.	System	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User entered empty.	System	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:51:31
User entered empty.	System	13 Apr 2021 19:25:23

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
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.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:53:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 10:53:55
Data point term sent to Coder	System	13 Apr 2021 19:26:49
User entered 'heparin'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered 'pci'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered '2'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered 'Other (OTHER)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered 'iu/ml'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User closed query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 19:28:03
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	13 Apr 2021 19:28:03
User entered 'once (ONCE)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:28:03
User opened query 'Data is required. Please complete.' (Site from System).	System	13 Apr 2021 19:25:56
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered '0'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:31:57
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User entered empty.	System	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User entered empty.	System	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:46
User entered empty.	System	13 Apr 2021 19:25:56

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: VASODILATORS USED IN CARDIAC DISEASES, ATC: ORGANIC NITRATES, PRODUCT: GLYCERYL TRINITRATE, PRODUCTSYNONYM: NITROGLYCERIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:17:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Apr 2021 13:17:55
Data point term sent to Coder	System	13 Apr 2021 19:29:55
User entered 'nitroglycerin'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered 'acute chest pain'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered '200'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered 'ug (ug)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:00
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User entered empty.	System	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User entered empty.	System	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:52:56
User entered empty.	System	13 Apr 2021 19:29:51

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: PLATELET AGGREGATION INHIBITORS EXCL. HEPARIN, PRODUCT: CLOPIDOGREL BISULFATE, PRODUCTSYNONYM: PLAVIX - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 19:48:54
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	13 Apr 2021 19:48:54
Data point term sent to Coder	System	13 Apr 2021 19:30:56
User entered 'plavix'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered 'thrombolic event prevention'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered '600'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered empty.	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered '0'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered '03 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:29:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Apr 2021 12:32:04
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User entered empty.	System	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User entered empty.	System	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:26:23

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:53:54
User entered empty.	System	13 Apr 2021 19:30:50

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:26:23

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:20
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 13:25:46
User entered 'No (N)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	29 Sep 2020 17:10:26
User entered 'Yes (Y)' reason for change: Data Entry Error	Jacob sekinger (b) (4)	29 Sep 2020 17:09:59
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 20:16:22

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:23

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:32:29
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '9 Dec 2020'	Melissa Fuson (b) (4)	17 Dec 2020 13:28:09

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:23

[Procedure/Surgery](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:32:29
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '2 CORONARY ARTERY STENTS PLACED FOR MYOCARDIAL INFARCTION AE'	(b) (4) Melissa Fuson (b) (4)	17 Dec 2020 13:28:09

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:32:29
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Adverse Event (AE)'	Melissa Fuson (b) (4)	17 Dec 2020 13:28:09

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:26:23

If indication is Other, specify

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:32:29
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 13:28:09

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:26:23

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:18
DataPoint Verified.		15 Apr 2021 12:32:34
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '03 Feb 2021'	(b) (4) Steven Anderson (b) (4) (b) (4)	08 Feb 2021 21:26:14

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:26:23

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:18
DataPoint Verified.		15 Apr 2021 12:32:34
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'echocardiogram'	(b) (4) Steven Anderson (b) (4) (b) (4)	08 Feb 2021 21:26:14

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:18
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:32:34
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4)	08 Feb 2021 21:26:14

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:26:23

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:18
DataPoint Verified.		15 Apr 2021 12:32:34
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	(b) (4) Steven Anderson (b) (4) (b) (4)	08 Feb 2021 21:26:14

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:26:23

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:19
DataPoint Un-verified.		15 Apr 2021 12:32:58
DataPoint Verified.		15 Apr 2021 12:32:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	
User entered '01 Jan 2021' reason for change: Data Entry Error	System	01 Apr 2021 18:35:10
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 18:35:10
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	01 Apr 2021 18:34:33
User entered '00 Jan 2021' (non-conformant).	System	01 Apr 2021 18:34:33
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4), (b) (6)	01 Apr 2021 18:34:33
User entered 'UN Jan 2021' (non-conformant).	System	01 Apr 2021 18:34:10
	(b) (4), (b) (6)	01 Apr 2021 18:34:10

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:26:23

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:19
DataPoint Un-verified.		15 Apr 2021 12:32:58
DataPoint Verified.		15 Apr 2021 12:32:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'nasopharyngoscopy'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:34:10

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:26:23

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:19
DataPoint Un-verified.		15 Apr 2021 12:32:58
DataPoint Verified.		15 Apr 2021 12:32:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'Adverse Event (AE)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:34:10

US3412016

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:26:23

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:39:19
DataPoint Un-verified.	(b) (4), (b) (6)	15 Apr 2021 12:32:58
DataPoint Verified.	(b) (4), (b) (6)	15 Apr 2021 12:32:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 18:34:10

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'USA-US061-2020-MRNA-1273-P301000018'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:06:46
Signature has been broken.	System	13 Apr 2021 17:11:39
User entered 'Yes (Y)'	System	13 Apr 2021 17:11:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
	(b) (4)	
Un-reviewed for Safety.	System	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'No (N)'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 16:46:17
Reviewed for Safety.		09 Feb 2021 17:31:24
Un-reviewed for Safety.	System	08 Feb 2021 21:08:45
DataPoint Un-verified.	System	08 Feb 2021 21:08:45
User entered 'Yes (Y)'	System	08 Feb 2021 21:08:45
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Richard'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'Gregory'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Powell'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Gottschlich'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'Cincinnati'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'OH'	(b) (4) System	02 Apr 2021 17:24:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered '45242'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:15:54
DataPoint Verified.		15 Dec 2020 22:27:10
User entered 'US'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	02 Apr 2021 17:24:25
User entered '4'	System	22 Feb 2021 17:24:10
User entered '3'	System	09 Feb 2021 17:30:48
User entered '2'	System	16 Dec 2020 19:16:33
User entered '1'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'USA-US061-2020-MRNA-1273-P301000018'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:00
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:06:46
Signature has been broken.	System	13 Apr 2021 17:11:39
User entered 'Yes (Y)'	System	13 Apr 2021 17:11:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'No (N)'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:46:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 17:31:24
Un-reviewed for Safety.	System	08 Feb 2021 21:08:45
DataPoint Un-verified.	System	08 Feb 2021 21:08:45
User entered 'Yes (Y)'	System	08 Feb 2021 21:08:45
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Richard'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Gregory'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Powell'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Gottschlich'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Cincinnati'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'OH'	(b) (4) System	02 Apr 2021 17:24:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered '45242'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 19:15:54
DataPoint Verified.		15 Dec 2020 22:27:10
User entered 'US'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	02 Apr 2021 17:24:25
User entered '4'	System	22 Feb 2021 17:24:10
User entered '3'	System	09 Feb 2021 17:30:48
User entered '2'	System	16 Dec 2020 19:16:33
User entered '1'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:26:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:27:10
User entered '15/Dec/2020 20:03'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:26:23

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)	05 Apr 2021 14:58:13
Reviewed for Safety.	(b) (4), (b) (6)	16 Dec 2020 19:15:54
DataPoint Verified.		15 Dec 2020 22:27:10
User entered '1'		15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'USA-US061-2020-MRNA-1273-P301000018'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:06:46
Signature has been broken.	System	13 Apr 2021 17:11:39
User entered 'Yes (Y)'	System	13 Apr 2021 17:11:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
	(b) (4)	
Un-reviewed for Safety.	System	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'No (N)'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
	(b) (4), (b) (6)	
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:46:17
Reviewed for Safety.		09 Feb 2021 17:31:24
Un-reviewed for Safety.	System	08 Feb 2021 21:08:45
DataPoint Un-verified.	System	08 Feb 2021 21:08:45
User entered 'Yes (Y)'	System	08 Feb 2021 21:08:45
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Richard'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Gregory'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Powell'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Gottschlich'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Cincinnati'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'OH'	(b) (4) System	02 Apr 2021 17:24:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered '45242'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Reviewed for Safety.	(b) (4)	16 Dec 2020 19:15:54
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
User entered 'US'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	02 Apr 2021 17:24:25
User entered '4'	System	22 Feb 2021 17:24:10
User entered '3'	System	09 Feb 2021 17:30:48
User entered '2'	System	16 Dec 2020 19:16:33
User entered '1'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:26:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:46:17
User entered '16/Dec/2020 14:16'	System	16 Dec 2020 19:16:33

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:26:23

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)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:46:17
Reviewed for Safety.		09 Feb 2021 17:31:24
User entered '1' reason for change: Data Entry Error		16 Dec 2020 19:16:33
User entered '0'		16 Dec 2020 19:16:09

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'USA-US061-2020-MRNA-1273-P301000018'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:06:46
Signature has been broken.	System	13 Apr 2021 17:11:39
User entered 'Yes (Y)'	System	13 Apr 2021 17:11:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
	(b) (4)	
Un-reviewed for Safety.	System	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'No (N)'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Mar 2021 16:46:17
Reviewed for Safety.		09 Feb 2021 17:31:24
Un-reviewed for Safety.	System	08 Feb 2021 21:08:45
DataPoint Un-verified.	System	08 Feb 2021 21:08:45
User entered 'Yes (Y)'	System	08 Feb 2021 21:08:45
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Richard'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Gregory'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Powell'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Gottschlich'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Cincinnati'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'OH'	(b) (4) System	02 Apr 2021 17:24:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered '45242'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:15:54
DataPoint Verified.		15 Dec 2020 22:27:10
User entered 'US'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	02 Apr 2021 17:24:25
User entered '4'	System	22 Feb 2021 17:24:10
User entered '3'	System	09 Feb 2021 17:30:48
User entered '2'	System	16 Dec 2020 19:16:33
User entered '1'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:26:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:46:17
User entered '09/Feb/2021 12:30'	System	09 Feb 2021 17:30:48

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:26:23

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)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:46:17
Reviewed for Safety.		09 Feb 2021 17:31:24
User entered '1'		09 Feb 2021 17:30:48

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'USA-US061-2020-MRNA-1273-P301000018'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:06:46
Signature has been broken.	System	13 Apr 2021 17:11:39
User entered 'Yes (Y)'	System	13 Apr 2021 17:11:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
	(b) (4)	
Un-reviewed for Safety.	System	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'No (N)'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:46:17
Reviewed for Safety.	(b) (4), (b) (6)	09 Feb 2021 17:31:24
Un-reviewed for Safety.	System	08 Feb 2021 21:08:45
DataPoint Un-verified.	System	08 Feb 2021 21:08:45
User entered 'Yes (Y)'	System	08 Feb 2021 21:08:45
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Richard'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Gregory'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Powell'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Gottschlich'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

Site Address: [Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

Site Address: [City](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Cincinnati'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'OH'	(b) (4) System	02 Apr 2021 17:24:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered '45242'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:15:54
DataPoint Verified.		15 Dec 2020 22:27:10
User entered 'US'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	02 Apr 2021 17:24:25
User entered '4'	System	22 Feb 2021 17:24:10
User entered '3'	System	09 Feb 2021 17:30:48
User entered '2'	System	16 Dec 2020 19:16:33
User entered '1'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:26:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 16:46:17
User entered '22/Feb/2021 11:24'	System	22 Feb 2021 17:24:10

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:26:23

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)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:46:17
Reviewed for Safety.		22 Feb 2021 17:24:17
User entered '1'		22 Feb 2021 17:24:10

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'USA-US061-2020-MRNA-1273-P301000018'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:52:00
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:06:46
Signature has been broken.	System	13 Apr 2021 17:11:39
User entered 'Yes (Y)'	System	13 Apr 2021 17:11:39
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
	(b) (4)	
Un-reviewed for Safety.	System	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'No (N)'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Yes (Y)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	25 Mar 2021 16:46:17
Reviewed for Safety.		09 Feb 2021 17:31:24
Un-reviewed for Safety.	System	08 Feb 2021 21:08:45
DataPoint Un-verified.	System	08 Feb 2021 21:08:45
User entered 'Yes (Y)'	System	08 Feb 2021 21:08:45
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4)	15 Dec 2020 22:27:10
Reviewed for Safety.	(b) (4), (b) (6)	15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'No (N)'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's First Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Richard'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Gregory'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator's Last Name](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered 'Powell'	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Gottschlich'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: Street](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered '4260 Glendale Milford Road'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

Site Address: City

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered 'Cincinnati'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: State](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'OH'	(b) (4) System	02 Apr 2021 17:24:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Un-reviewed for Safety.	(b) (4)	02 Apr 2021 17:24:25
DataPoint Un-verified.	System	02 Apr 2021 17:24:25
User entered empty.	System	02 Apr 2021 17:24:25
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 22:27:10
Reviewed for Safety.		15 Dec 2020 20:03:45
User entered '45242'	System	15 Dec 2020 20:03:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
Reviewed for Safety.	(b) (4) (b) (4), (b) (6)	16 Dec 2020 19:15:54
DataPoint Verified.		15 Dec 2020 22:27:10
User entered 'US'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form

Generated On: 09 Jun 2021 17:26:23

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '5'	System	02 Apr 2021 17:24:25
User entered '4'	System	22 Feb 2021 17:24:10
User entered '3'	System	09 Feb 2021 17:30:48
User entered '2'	System	16 Dec 2020 19:16:33
User entered '1'	System	15 Dec 2020 20:03:51

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:26:23

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered '02/Apr/2021 17:24'	(b) (4) System	02 Apr 2021 17:24:25

US3412016

Folder: SAE USA-US061-2020-MRNA-1273-P301000018

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:26:23

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:06:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:13
User entered 'I'	(b) (4) (b) (4), (b) (6)	02 Apr 2021 17:24:25