

US3412013 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:24:56

All time stamps listed in this document are displayed in GMT

US3412013

Form: Participant Creation

Data signed: (b) (4) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

Participant ID

US3412013

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

US3412013

Folder: Screening

Form: Visit Date

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

Generated On: 09 Jun 2021 17:24:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3412013

Folder: Screening

Form: Demographics

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

Generated On: 09 Jun 2021 17:24:56

Date of Birth (MMM yyyy)	(b) (6) 1962
Age	58
Age Units	YEARS
Age (Derived)	58
Sex	Female <input checked="" type="radio"/> Male <input type="radio"/>
Ethnicity	Hispanic or Latino <input type="radio"/> Not Hispanic or Latino <input checked="" type="radio"/> Not Reported <input type="radio"/> Unknown <input type="radio"/>
Race (Check All That Apply)	
White	True
Black	False
Asian	False
American Indian or Alaska Native	False
Native Hawaiian or other Pacific Islander	False
Other	False
If race is Other, specify _____	
Unknown	False
Not reported	False

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Folder: Screening

Form: Enrollment

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

Generated On: 09 Jun 2021 17:24:56

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	<input checked="" type="radio"/>
Amendment 2	<input type="radio"/>
Amendment 3	<input type="radio"/>
Amendment 4	<input type="radio"/>
Amendment 5	<input type="radio"/>

Was participant enrolled in the study?

Yes	<input checked="" type="radio"/>
No	<input type="radio"/>

If No, indicate reason for screen fail

Withdrew Consent	<input type="radio"/>
Inclusion/Exclusion	<input type="radio"/>
Cohort Full	<input type="radio"/>
Other	<input type="radio"/>

If reason for screen fail is Other, specify _____

Was this participant screened previously?

Yes	<input type="radio"/>
No	<input checked="" type="radio"/>

If Yes, previous participant number _____

Enrollment Trigger 1

US3412013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

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

Generated On: 09 Jun 2021 17:24:56

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

US3412013

Folder: Screening

Form: Medical History Summary

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

Generated On: 09 Jun 2021 17:24:56

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

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)	_____

US3412013

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

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)	

US3412013

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

Condition	GERD
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)	_____

US3412013

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

Condition	CHRONIC LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2007
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 2007
Start Year (derived)	2007
Stop Month and Year (derived)	
Stop Year (derived)	

US3412013

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

Condition	DIABETES TYPE II
Start date (dd MMM yyyy)	UN UNK 2005
Start date completely unknown	False
Condition ongoing at study entry	Yes <input checked="" type="radio"/> No <input type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2005
Start Year (derived)	2005
Stop Month and Year (derived)	
Stop Year (derived)	

US3412013

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

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

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

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

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Folder: Screening

Form: Medical History (8)

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

Condition	FEVER BLISTERS
Start date (dd MMM yyyy)	UN UNK 1965
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 1965
Start Year (derived)	1965
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

Condition	DYSAUTONOMIA
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)	

US3412013

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

Condition	POST MENOPAUSAL
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)	

US3412013

Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

Condition	ECZEMA
Start date (dd MMM yyyy)	UN UNK 1995
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 1995
Start Year (derived)	1995
Stop Month and Year (derived)	
Stop Year (derived)	

US3412013

Folder: Screening

Form: Vital Signs

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

Generated On: 09 Jun 2021 17:24:56

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)	12:05 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 12:05
Height (xxx.x)	167.5 cm
Weight (xxx.x)	87.6 kg
BMI (xxx.x)	31.22299 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 04:21:13

Generated On: 09 Jun 2021 17:24:56

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.

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Folder: Screening

Form: Childbearing Potential

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

Generated On: 09 Jun 2021 17:24:56

Date of assessment (dd MMM yyyy) 29 JUL 2020

Is the participant of childbearing potential? Yes ☐
No ☒

If No, what is the reason? Surgically sterile ☐
Post-menopausal ☒
Partner medically sterile ☐
Not reached age of Menarche ☐
Other ☐

If Partner medically sterile or Other, specify _____

If Surgically sterile, date of surgery (dd MMM yyyy) _____

Date of surgery unknown False

If Post-menopausal, date of last menstruation (dd MMM yyyy) UN UNK 2008

Date of last menstruation unknown False

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Folder: Screening

Form: Risk of Exposure

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

Generated On: 09 Jun 2021 17:24:56

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

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

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	29 JUL 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

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

What was the participant's randomization number? 142255

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

Height	ND - Not Done
Weight	ND - Not Done

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

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)	12:05 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 12:05
Temperature (xxx.x)	36.8 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	82 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	76 mmHg
Diastolic Blood Pressure units	MMHG

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

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)	13:35 (24 HR)
Vital Signs Date and Time (derived)	29 JUL 2020 13:35
Temperature (xxx.x)	97.3 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	75 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	125 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	70 mmHg
Diastolic Blood Pressure units	MMHG

US3412013

Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

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) 13:00 (24 HR)

Treatment Date and Time (derived) 29 JUL 2020 13:00

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 00:40:45

Generated On: 09 Jun 2021 17:24:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	29 JUL 2020
Collection time (00:00-23:59)	12:25 (24 HR)
Collection date and time (derived)	29 JUL 2020 12:25

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:40:43

Generated On: 09 Jun 2021 17:24:56

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	12:37	29 JUL 2020 12:37
Nasopharyngeal Swab 2	No		

US3412013

Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:43

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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

97.3 °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

29 JUL 2020 13:39

PC Open Date & Time

29 JUL 2020 13:20

PC Close Date & Time

29 JUL 2020 15:50

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 98.2 °F

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

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

PC Time Stamp	29 JUL 2020 20:05
PC Open Date & Time	29 JUL 2020 16:45
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 17:24:56

TIMEPOINT

DAY 2

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °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 12:37

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

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Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

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

31 JUL 2020 12:55

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 AUG 2020 18:24

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

02 AUG 2020 13:03

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

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

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 AUG 2020 12:38

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

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

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 11:30

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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 13:42

PC Open Date & Time

29 JUL 2020 13:20

PC Close Date & Time

29 JUL 2020 15:50

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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 20:03

PC Open Date & Time

29 JUL 2020 16:45

PC Close Date & Time

30 JUL 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

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 12:38

PC Open Date & Time

30 JUL 2020 12:00

PC Close Date & Time

31 JUL 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

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 12:56

PC Open Date & Time

31 JUL 2020 12:00

PC Close Date & Time

01 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

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 18:25

PC Open Date & Time

01 AUG 2020 12:00

PC Close Date & Time

02 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

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 13:03

PC Open Date & Time

02 AUG 2020 12:00

PC Close Date & Time

03 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

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 14:45

PC Open Date & Time

03 AUG 2020 12:00

PC Close Date & Time

04 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

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

05 AUG 2020 11:30

PC Open Date & Time

04 AUG 2020 12:00

PC Close Date & Time

05 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 13:43
PC Open Date & Time	29 JUL 2020 13:20
PC Close Date & Time	29 JUL 2020 15:50

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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

No ☒

Yes ☐

PC Time stamp	29 JUL 2020 20:03
PC Open Date & Time	29 JUL 2020 16:45
PC Close Date & Time	30 JUL 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

53 of 3357

EAB) (1725)

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

Yes <input type="checkbox"/>	
PC Time stamp	30 JUL 2020 12:38
PC Open Date & Time	30 JUL 2020 12:00
PC Close Date & Time	31 JUL 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

55 of 3357

EAB) (1725)

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

Yes <input type="checkbox"/>	
PC Time stamp	31 JUL 2020 12:57
PC Open Date & Time	31 JUL 2020 12:00
PC Close Date & Time	01 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 4

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

57 of 3357

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

Yes <input type="checkbox"/>	
PC Time stamp	01 AUG 2020 18:25
PC Open Date & Time	01 AUG 2020 12:00
PC Close Date & Time	02 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

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

59 of 3357

EAB) (1725)

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

Yes <input type="checkbox"/>	
PC Time stamp	02 AUG 2020 13:04
PC Open Date & Time	02 AUG 2020 12:00
PC Close Date & Time	03 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

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

61 of 3357

EAB) (1725)

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

Yes <input type="checkbox"/>	
PC Time stamp	03 AUG 2020 14:45
PC Open Date & Time	03 AUG 2020 12:00
PC Close Date & Time	04 AUG 2020 11:59

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

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

63 of 3357

EAB) (1725)

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 11:30
PC Open Date & Time	04 AUG 2020 12:00
PC Close Date & Time	05 AUG 2020 11:59

US3412013

Folder: Safety Call Day 8 (1)

Form: Safety Call

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

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Safety Call Day 8 (1)

Form: Continuing

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

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 15 (1)

Form: Safety Call

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

Generated On: 09 Jun 2021 17:24:56

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 12 AUG 2020

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

Comments

If Contact Not Made, please provide Comments

US3412013

Folder: Safety Call Day 15 (1)

Form: Continuing

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

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 22 (1)

Form: Safety Call

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

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Safety Call Day 22 (1)

Form: Continuing

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

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	26 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

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)	11:06 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 11:06
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	90 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	115 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

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)	12:35 (24 HR)
Vital Signs Date and Time (derived)	26 AUG 2020 12:35
Temperature (xxx.x)	97.8 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	84 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	18 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	128 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

US3412013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

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.

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

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) 12:05 (24 HR)

Treatment Date and Time (derived) 26 AUG 2020 12:05

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

US3412013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

26 AUG 2020

Collection time (00:00-23:59)

11:40 (24 HR)

Collection date and time (derived)

26 AUG 2020 11:40

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

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	11:49	26 AUG 2020 11:49
Nasopharyngeal Swab 2	No		

US3412013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

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

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

26 AUG 2020 12:37

PC Open Date & Time

26 AUG 2020 12:25

PC Close Date & Time

26 AUG 2020 14:55

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 1, AFTER VACCINATION
(AT HOME)

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

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

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

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

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

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

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

Was **TEMPERATURE** taken? Yes ☒ No ☐

Please record your **TEMPERATURE** in °F 97.9 °F

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

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

PC Time Stamp	26 AUG 2020 18:59
PC Open Date & Time	26 AUG 2020 15:50
PC Close Date & Time	27 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

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

100.2 °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):

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

True

To **PREVENT** pain or fever from occurring

False

PC Time Stamp

27 AUG 2020 14:13

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

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

98.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

28 AUG 2020 18:03

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 4

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.7 °F

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

Yes ☐

No ☒

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

PC Time Stamp

29 AUG 2020 18:04

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

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

97.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

30 AUG 2020 19:41

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.9 °F

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

Yes ☐

No ☒

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

PC Time Stamp

31 AUG 2020 15:27

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

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.

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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

98.2 °F

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

Yes ☐

No ☒

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

PC Time Stamp

01 SEP 2020 17:16

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

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

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

26 AUG 2020 12:37

PC Open Date & Time

26 AUG 2020 12:25

PC Close Date & Time

26 AUG 2020 14:55

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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 19:00

PC Open Date & Time

26 AUG 2020 15:50

PC Close Date & Time

27 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

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 14:14

PC Open Date & Time

27 AUG 2020 12:00

PC Close Date & Time

28 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

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 18:03

PC Open Date & Time

28 AUG 2020 12:00

PC Close Date & Time

29 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

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 18:05

PC Open Date & Time

29 AUG 2020 12:00

PC Close Date & Time

30 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

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 19:42

PC Open Date & Time

30 AUG 2020 12:00

PC Close Date & Time

31 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

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

31 AUG 2020 15:27

PC Open Date & Time

31 AUG 2020 12:00

PC Close Date & Time

01 SEP 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

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

01 SEP 2020 17:17

PC Open Date & Time

01 SEP 2020 12:00

PC Close Date & Time

02 SEP 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 12:38
PC Open Date & Time	26 AUG 2020 12:25
PC Close Date & Time	26 AUG 2020 14:55

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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

No ☒

Yes ☐

PC Time stamp	26 AUG 2020 19:01
PC Open Date & Time	26 AUG 2020 15:50
PC Close Date & Time	27 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 2

HEADACHE

None ☐

No interference with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☒

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☐

No interference with activity ☒

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

Yes <input type="checkbox"/>	
PC Time stamp	27 AUG 2020 14:15
PC Open Date & Time	27 AUG 2020 12:00
PC Close Date & Time	28 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

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EAB) (1725)

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

Yes <input type="checkbox"/>	
PC Time stamp	28 AUG 2020 18:04
PC Open Date & Time	28 AUG 2020 12:00
PC Close Date & Time	29 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

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 ☒

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

Yes <input type="checkbox"/>	
PC Time stamp	29 AUG 2020 18:05
PC Open Date & Time	29 AUG 2020 12:00
PC Close Date & Time	30 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

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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US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

Yes <input type="checkbox"/>	
PC Time stamp	30 AUG 2020 19:42
PC Open Date & Time	30 AUG 2020 12:00
PC Close Date & Time	31 AUG 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

Yes <input type="checkbox"/>	
PC Time stamp	31 AUG 2020 15:28
PC Open Date & Time	31 AUG 2020 12:00
PC Close Date & Time	01 SEP 2020 11:59

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

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 ☒

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Safety Call Day 36 (1)

Form: Safety Call

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

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Safety Call Day 36 (1)

Form: Continuing

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

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:40:43

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:43

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 00:40:43

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:43

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	24 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

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

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) _____

US3412013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

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.

US3412013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	24 SEP 2020
Collection time (00:00-23:59)	12:09 (24 HR)
Collection date and time (derived)	24 SEP 2020 12:09

US3412013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 00:40:45

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 64
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	False
Chills	False
Cough	True
Shortness of breath	False
Difficulty breathing	True
Fatigue	True
Muscle aches	False
Body aches	False
Headache	True
New loss of taste	True
New loss of smell	True
Sore throat	True
Congestion	True
Runny nose	True
Nausea	False
Vomiting	False
Diarrhea	False
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Date and time of submission	01 OCT 2020 15:53:07
Patient Cloud Open Date & Time	28 SEP 2020 00:01
Patient Cloud Close Date & Time	02 OCT 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

07 OCT 2020 18:04:30

Patient Cloud Open Date & Time

05 OCT 2020 00:01

Patient Cloud Close Date & Time

09 OCT 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 78
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	12 OCT 2020 00:02:15
Patient Cloud Open Date & Time	12 OCT 2020 00:01
Patient Cloud Close Date & Time	16 OCT 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 12:25:54

Patient Cloud Open Date & Time

26 OCT 2020 00:01

Patient Cloud Close Date & Time

30 OCT 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 99
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 NOV 2020 06:20:59
Patient Cloud Open Date & Time	02 NOV 2020 00:01
Patient Cloud Close Date & Time	06 NOV 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 17:55:48

Patient Cloud Open Date & Time

09 NOV 2020 00:01

Patient Cloud Close Date & Time

13 NOV 2020 23:59

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 18:28:44

Patient Cloud Open Date & Time

16 NOV 2020 00:01

Patient Cloud Close Date & Time

20 NOV 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 117
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	22 NOV 2020 14:17:15
Patient Cloud Open Date & Time	20 NOV 2020 00:01
Patient Cloud Close Date & Time	24 NOV 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

27 NOV 2020 13:54:58

Patient Cloud Open Date & Time

27 NOV 2020 00:01

Patient Cloud Close Date & Time

01 DEC 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 20:56:42

Patient Cloud Open Date & Time

04 DEC 2020 00:01

Patient Cloud Close Date & Time

08 DEC 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

11 DEC 2020 23:32:12

Patient Cloud Open Date & Time

11 DEC 2020 00:01

Patient Cloud Close Date & Time

15 DEC 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 18:40:37

Patient Cloud Open Date & Time

18 DEC 2020 00:01

Patient Cloud Close Date & Time

22 DEC 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

28 DEC 2020 14:40:18

Patient Cloud Open Date & Time

25 DEC 2020 00:01

Patient Cloud Close Date & Time

29 DEC 2020 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	02 JAN 2021 11:14:59
Patient Cloud Open Date & Time	01 JAN 2021 00:01
Patient Cloud Close Date & Time	05 JAN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 166
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	10 JAN 2021 18:15:41
Patient Cloud Open Date & Time	08 JAN 2021 00:01
Patient Cloud Close Date & Time	12 JAN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 00:03:16

Patient Cloud Open Date & Time

15 JAN 2021 00:01

Patient Cloud Close Date & Time

19 JAN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 00:01:51

Patient Cloud Open Date & Time

22 JAN 2021 00:01

Patient Cloud Close Date & Time

26 JAN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

02 FEB 2021 12:20:34

Patient Cloud Open Date & Time

29 JAN 2021 00:01

Patient Cloud Close Date & Time

02 FEB 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 194
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Date and time of submission	05 FEB 2021 00:02:56
Patient Cloud Open Date & Time	05 FEB 2021 00:01
Patient Cloud Close Date & Time	09 FEB 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 05:23:17

Patient Cloud Open Date & Time

12 FEB 2021 00:01

Patient Cloud Close Date & Time

16 FEB 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 16:55:00

Patient Cloud Open Date & Time

19 FEB 2021 00:01

Patient Cloud Close Date & Time

23 FEB 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 215

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 FEB 2021 18:13:03

Patient Cloud Open Date & Time

26 FEB 2021 00:01

Patient Cloud Close Date & Time

02 MAR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

09 MAR 2021 10:53:25

Patient Cloud Open Date & Time

05 MAR 2021 00:01

Patient Cloud Close Date & Time

09 MAR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 00:01:56

Patient Cloud Open Date & Time

12 MAR 2021 00:01

Patient Cloud Close Date & Time

16 MAR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 04:53:46

Patient Cloud Open Date & Time

19 MAR 2021 00:01

Patient Cloud Close Date & Time

23 MAR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 243

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

No ☒

Yes ☐

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

No ☒

Yes ☐

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

Date and time of submission

28 MAR 2021 12:46:51

Patient Cloud Open Date & Time

26 MAR 2021 00:01

Patient Cloud Close Date & Time

30 MAR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 250
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

02 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

06 APR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 257

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

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

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

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

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

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

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

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

09 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

13 APR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

20 APR 2021 20:35:36

Patient Cloud Open Date & Time

16 APR 2021 00:01

Patient Cloud Close Date & Time

20 APR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 18:43:40

Patient Cloud Open Date & Time

23 APR 2021 00:01

Patient Cloud Close Date & Time

27 APR 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

03 MAY 2021 11:01:26

Patient Cloud Open Date & Time

30 APR 2021 00:01

Patient Cloud Close Date & Time

04 MAY 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 285

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

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

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

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

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

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

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

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

07 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

11 MAY 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 MAY 2021 00:01
Patient Cloud Close Date & Time	18 MAY 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

21 MAY 2021 00:01

[Patient Cloud Close Date & Time](#)

25 MAY 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 306
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 313
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

04 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

08 JUN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 JUN 2021 00:01
Patient Cloud Close Date & Time	15 JUN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

18 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

22 JUN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JUN 2021 00:01
Patient Cloud Close Date & Time	29 JUN 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 348
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

09 JUL 2021 00:01

[Patient Cloud Close Date & Time](#)

13 JUL 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	16 JUL 2021 00:01
Patient Cloud Close Date & Time	20 JUL 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	23 JUL 2021 00:01
Patient Cloud Close Date & Time	27 JUL 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

06 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

10 AUG 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	13 AUG 2021 00:01
Patient Cloud Close Date & Time	17 AUG 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 390

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	20 AUG 2021 00:01
Patient Cloud Close Date & Time	24 AUG 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 <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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

17 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

21 SEP 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 425

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

24 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

28 SEP 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 446

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

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

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

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

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

Fever (Temperature \geq 100.4°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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 453
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	22 OCT 2021 00:01
Patient Cloud Close Date & Time	26 OCT 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

29 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

02 NOV 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

05 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

09 NOV 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 NOV 2021 00:01
Patient Cloud Close Date & Time	16 NOV 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

26 NOV 2021 00:01

[Patient Cloud Close Date & Time](#)

30 NOV 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

03 DEC 2021 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 DEC 2021 00:01
Patient Cloud Close Date & Time	14 DEC 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 <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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	17 DEC 2021 00:01
Patient Cloud Close Date & Time	21 DEC 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	24 DEC 2021 00:01
Patient Cloud Close Date & Time	28 DEC 2021 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	31 DEC 2021 00:01
Patient Cloud Close Date & Time	04 JAN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 530

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

07 JAN 2022 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	14 JAN 2022 00:01
Patient Cloud Close Date & Time	18 JAN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

04 FEB 2022 00:01

[Patient Cloud Close Date & Time](#)

08 FEB 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 FEB 2022 00:01
Patient Cloud Close Date & Time	15 FEB 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Close Date & Time](#)

22 FEB 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Close Date & Time](#)

01 MAR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 586

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

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

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

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

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

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

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

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Close Date & Time](#)

08 MAR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	11 MAR 2022 00:01
Patient Cloud Close Date & Time	15 MAR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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="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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 MAR 2022 00:01
Patient Cloud Close Date & Time	22 MAR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	25 MAR 2022 00:01
Patient Cloud Close Date & Time	29 MAR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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

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

[Patient Cloud Close Date & Time](#)

05 APR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

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

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 APR 2022 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 628

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

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

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

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

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

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

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

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 635
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

06 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

10 MAY 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

13 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

17 MAY 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

20 MAY 2022 00:01

[Patient Cloud Close Date & Time](#)

24 MAY 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

03 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

07 JUN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 684
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	10 JUN 2022 00:01
Patient Cloud Close Date & Time	14 JUN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

17 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

21 JUN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

24 JUN 2022 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

01 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

05 JUL 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	08 JUL 2022 00:01
Patient Cloud Close Date & Time	12 JUL 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

Date and time of submission	
Patient Cloud Open Date & Time	15 JUL 2022 00:01
Patient Cloud Close Date & Time	19 JUL 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	22 JUL 2022 00:01
Patient Cloud Close Date & Time	26 JUL 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT	DAY 740
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

05 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

09 AUG 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

DAY 747

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

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

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

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

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

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

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

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	12 AUG 2022 00:01
Patient Cloud Close Date & Time	16 AUG 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 <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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

19 AUG 2022 00:01

[Patient Cloud Close Date & Time](#)

23 AUG 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 <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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

[Patient Cloud Open Date & Time](#)

02 SEP 2022 00:01

[Patient Cloud Close Date & Time](#)

06 SEP 2022 23:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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°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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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"/>

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:24:56

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		12 MAR 2021 00:02:23

US3412013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 10 Mar 2021 19:25:52

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 JAN 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412013

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

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

Visit date (dd MMM yyyy)	02 MAR 2021
--------------------------	-------------

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

Folder OID	VISIT4
------------	--------

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

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) _____

US3412013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

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.

US3412013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	02 MAR 2021
Collection time (00:00-23:59)	13:35 (24 HR)
Collection date and time (derived)	02 MAR 2021 13:35

US3412013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 MAR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412013

Folder: Safety Call Day 239 (1)

Form: Continuing

Data signed: (b) (4) 05 Apr 2021 14:58:01

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Data signed: (b) (4) 26 Apr 2021 14:38:04

Generated On: 09 Jun 2021 17:24:56

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

21 APR 2021

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412013

Folder: Safety Call Day 269 (1)

Form: Continuing

Data signed: (b) (4) 26 Apr 2021 14:38:04

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412013

Folder: Safety Call Day 299 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Safety Call Day 299 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

Is the participant continuing to the next visit?

Yes ☐

No ☐

Continuing Flag

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Date of Contact	02 OCT 2020
Time of Contact	11:00
Date and Time of Contact (derived)	02 OCT 2020 11:00
Type of Contact	Clinic Visit - Scheduled <input type="checkbox"/>
	Clinical Visit - Unscheduled <input checked="" type="checkbox"/>
	Safety Call <input type="checkbox"/>
	Convalescent Tele-visit <input type="checkbox"/>
Has the subject reported symptoms of SARS-COV-2?	Yes <input checked="" type="checkbox"/>
	No <input type="checkbox"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input checked="" type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	02 OCT 2020
------	-------------

Assessment Not Done	False
---------------------	-------

O2 Saturation	ND - Not Done
---------------	---------------

O2 Saturation Units	%
---------------------	---

Temperature	36.9 C
-------------	--------

Chills	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Cough	None <input type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input checked="" type="radio"/>
	Not Done <input type="radio"/>

Shortness of Breath	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>
	Not Done <input type="radio"/>

Difficulty Breathing	None <input checked="" type="radio"/>
	Mild <input type="radio"/>
	Moderate <input type="radio"/>
	Severe <input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Not Done	<input type="radio"/>
Fatigue	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input checked="" type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	03 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.7 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input checked="" type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	04 OCT 2020	
Assessment Not Done	False	
O2 Saturation	97 %	
O2 Saturation Units	%	
Temperature	97.3 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input checked="" type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	05 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input checked="" type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	06 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	98.2 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input checked="" type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input checked="" type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	07 OCT 2020	
Assessment Not Done	False	
O2 Saturation	98 %	
O2 Saturation Units	%	
Temperature	97.4 F	
Chills	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Cough	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Shortness of Breath	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Difficulty Breathing	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>

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Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Not Done	<input type="radio"/>
Fatigue	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Muscle Aches (Myalgia)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Body Aches	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Headache	None	<input type="radio"/>
	Mild	<input checked="" type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Taste	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
New Loss of Smell	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Nasal Congestion	None	<input type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input checked="" type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Runny Nose (Rhinorrhea)	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Nausea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Vomiting	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Diarrhea	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>
Sore Throat	None	<input checked="" type="radio"/>
	Mild	<input type="radio"/>
	Moderate	<input type="radio"/>
	Severe	<input type="radio"/>
	Not Done	<input type="radio"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input type="checkbox"/>
Day 3	<input checked="" type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	01 OCT 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	
---------------	--

O2 Saturation Units	
---------------------	--

Temperature	
-------------	--

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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EAB) (1725)

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Symptom Day

Day 1	<input checked="" type="radio"/>
Day 2	<input type="radio"/>
Day 3	<input type="radio"/>
Day 4	<input type="radio"/>
Day 5	<input type="radio"/>
Day 6	<input type="radio"/>
Day 7	<input type="radio"/>
Day 8	<input type="radio"/>
Day 9	<input type="radio"/>
Day 10	<input type="radio"/>
Day 11	<input type="radio"/>
Day 12	<input type="radio"/>
Day 13	<input type="radio"/>
Day 14	<input type="radio"/>
Day 15	<input type="radio"/>
Day 16	<input type="radio"/>
Day 17	<input type="radio"/>
Day 18	<input type="radio"/>
Day 19	<input type="radio"/>
Day 20	<input type="radio"/>
Day 21	<input type="radio"/>
Day 22	<input type="radio"/>
Day 23	<input type="radio"/>
Day 24	<input type="radio"/>
Day 25	<input type="radio"/>
Day 26	<input type="radio"/>
Day 27	<input type="radio"/>
Day 28	<input type="radio"/>
Day 29	<input type="radio"/>
Day 30	<input type="radio"/>
Day 31	<input type="radio"/>
Day 32	<input type="radio"/>

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Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>
Date	29 SEP 2020	
Assessment Not Done	True	
O2 Saturation	<input type="text"/>	
O2 Saturation Units	<input type="text"/>	
Temperature	<input type="text"/>	
Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

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EAB) (1725)

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Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Symptom Day

Day 1	<input type="checkbox"/>
Day 2	<input checked="" type="checkbox"/>
Day 3	<input type="checkbox"/>
Day 4	<input type="checkbox"/>
Day 5	<input type="checkbox"/>
Day 6	<input type="checkbox"/>
Day 7	<input type="checkbox"/>
Day 8	<input type="checkbox"/>
Day 9	<input type="checkbox"/>
Day 10	<input type="checkbox"/>
Day 11	<input type="checkbox"/>
Day 12	<input type="checkbox"/>
Day 13	<input type="checkbox"/>
Day 14	<input type="checkbox"/>
Day 15	<input type="checkbox"/>
Day 16	<input type="checkbox"/>
Day 17	<input type="checkbox"/>
Day 18	<input type="checkbox"/>
Day 19	<input type="checkbox"/>
Day 20	<input type="checkbox"/>
Day 21	<input type="checkbox"/>
Day 22	<input type="checkbox"/>
Day 23	<input type="checkbox"/>
Day 24	<input type="checkbox"/>
Day 25	<input type="checkbox"/>
Day 26	<input type="checkbox"/>
Day 27	<input type="checkbox"/>
Day 28	<input type="checkbox"/>
Day 29	<input type="checkbox"/>
Day 30	<input type="checkbox"/>
Day 31	<input type="checkbox"/>
Day 32	<input type="checkbox"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Day 33	<input type="checkbox"/>
	Day 34	<input type="checkbox"/>
	Day 35	<input type="checkbox"/>
	Day 36	<input type="checkbox"/>
	Day 37	<input type="checkbox"/>
	Day 38	<input type="checkbox"/>
	Day 39	<input type="checkbox"/>
	Day 40	<input type="checkbox"/>

Date	30 SEP 2020
------	-------------

Assessment Not Done	True
---------------------	------

O2 Saturation	<input type="text"/>
---------------	----------------------

O2 Saturation Units	<input type="text"/>
---------------------	----------------------

Temperature	<input type="text"/>
-------------	----------------------

Chills	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Cough	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Shortness of Breath	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

Difficulty Breathing	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

	Not Done	<input type="checkbox"/>
Fatigue	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Muscle Aches (Myalgia)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Body Aches	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Headache	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Taste	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
New Loss of Smell	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Nasal Congestion	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Runny Nose (Rhinorrhea)	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Nausea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Vomiting	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Diarrhea	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>
Sore Throat	None	<input type="checkbox"/>
	Mild	<input type="checkbox"/>
	Moderate	<input type="checkbox"/>
	Severe	<input type="checkbox"/>
	Not Done	<input type="checkbox"/>

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Date of Visit 02 OCT 2020

Was the Subject Tested For SARS-CoV-2 by RT-PCR? Yes ☒
No ☐

Did Subject Test Positive For SARS-CoV-2 by RT-PCR? Yes ☐
No ☒

Date of Test 02 OCT 2020

Type of Test Performed Nasopharyngeal Swab ☒
Nasal Swab ☐
Saliva Test ☐
Other ☐

Other, specify _____

Was this diagnostic test performed at a lab other than the Study Central Lab? Yes ☐
No ☒

If yes, provide lab information below

Lab/ Institution Test Performed _____

CLIA Certified? Yes ☐
No ☐

COVID-19 Positive (CSA Programming Field Only) 0

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Generate Next COVID-19 Assessment

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

[Generate Next COVID-19 Assessment](#)

Yes ☐

No ☒

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Folder: Illness Visit (1)

Form: Saliva Collection

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Visit	Was Saliva Collected?	Date of Collection
Day 3	Yes	04 OCT 2020
Day 5	Yes	06 OCT 2020
Day 7	NA (COVID-19 Negative)	
Day 9	NA (COVID-19 Negative)	
Day 14	NA (COVID-19 Negative)	
Day 21	NA (COVID-19 Negative)	
Day 28	NA (COVID-19 Negative)	

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Folder: Illness Visit Day 1 (1)

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	02 OCT 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SICKD1

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (dd MMM yyyy)	02 OCT 2020
Time of assessment (00:00-23:59)	11:25 (24 HR)
Vital Signs Date and Time (derived)	02 OCT 2020 11:25
Height (xxx.x)	167.5 cm
Weight (xxx.x)	87.3 kg
Temperature (xxx.x)	36.9 C
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	94 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	17 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	120 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	60 mmHg
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

US3412013

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

02 OCT 2020

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

US3412013

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Was Blood Sample Taken for Immunologic Assessment of
SARS_COV-2 Infection?

Yes ☒

No ☐

NA (COVID-19 Negative) ☐

Date of Collection

02 OCT 2020

US3412013

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

Form: Visit Date

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

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

Visit date (dd MMM yyyy)	18 JAN 2021
--------------------------	-------------

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

Folder OID	UNBLND_DECIDE
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US3412013

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

Form: Unblinding

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

Date of updated informed consent (dd MMM yyyy) 13 JAN 2021

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

Was the participant unblinded? Yes ☒ No ☐

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

Date of unblinding (dd MMM yyyy) 18 JAN 2021

Participant randomization assignment mRNA-1273 ☒ Placebo ☐

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

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

Will participant receive mRNA-1273? Yes ☐ No ☒

Placebo Only Flag _____
Continuing with mRNA-1273 _____

US3412013

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

18 JAN 2021

Collection time (00:00-23:59)

12:36 (24 HR)

Collection date and time (derived)

18 JAN 2021 12:36

US3412013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	18 JAN 2021
Collection time (00:00 - 23:59)	12:19
Collection Date and Time (derived)	18 JAN 2021 12:19

US3412013

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:24:54

Generated On: 09 Jun 2021 17:24:56

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

AEID

Adverse event

UPPER RESPIRATORY
INFECTION

Was this a medically-attended AE?

Yes ☐

No ☒

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

29 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

16 DEC 2020

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☒

Grade 2/Moderate ☐

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

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Folder: Adverse Events

Form: Adverse Events (1)

Data signed: (b) (4) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

AEID	USA-US061-2020-MRNA-1273-P30 1000014
Adverse event	CELLULITIS - LEFT HAND
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)	20 NOV 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)	12 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)	22 NOV 2020
Hospital Discharge Date (dd MMM yyyy)	24 NOV 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 (2)

Data signed: (b) (4) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

SUBJECT NOTICED US THROUGH E-DIARY THAT SHE HAD CONTACT WITH A MEDICAL PROVIDER. SHE WENT TO SEE HER PCP ON 20-NOV-2020 TO FOLLOW UP ON HER PERSISTENT COUGH. HE ADVISED HER ON SOME OTC MEDICATIONS TO TRY. SHE HAS YET TO TRY ANY HE RECOMMENDED. ON FRIDAY ENTRY SHE WAS BIT BY HER CAT ON HER LEFT HAND. ON SATURDAY 21NOV2020 SHE WENT TO GOOD SAM ER WITH REDNESS, SWELLING, AND PAIN IN HER LEFT HAND. SHE WAS TOLD TO WATCH AND WAIT AND RETURN IF WORSENER. SHE RETURNED TO GOOD SAM ER ON SUNDAY 22 NOV 2020 AND ADMITTED FOR A SEVERE INFECTION IN HER LEFT HAND DUE TO CATBITE. SHE HAS BEEN STARTED ON VANCOMYCIN IV AND IS WAITING FOR CONSULT FROM A HAND SURGEON THIS AFTERNOON. HER COUGH HAS ALSO WORSENER TODAY AND SHE IS DISCUSSING IT WITH HER HOSPITALIST TODAY.

SUBJECT WAS DISCHARGED FROM HOSPITAL

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Data signed: (b) (4) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

ON 24NOV2020. NEW
MEDICATIONS INCLUDE
LEVOFOXACIN,
METRONIDAZOLE,
OXYCODONE, AND IBUPROFEN.
REGARDING CONSULT WITH
HAND SURGEON, NO SURGERY
WAS REQUIRED, ONLY
DEBRIDEMENT OF SUBJECT'S
LEFT HAND. SUBJECT WILL
SCHEDULE FOLLOWUP WITH
HAND SURGEON AND HAS
FOLLOWUP WITH PCP ON
11DEC2020. SUBJECT FEELS SHE
IS IMPROVING.

AE RESOLVED: 12DEC2020

COUGH WAS DUE TO SIDE OF
EFFECT OF LISINOPRIL WHICH
HAS SINCE BEEN
DISCONTINUED;

PURULENT TISSUE CULTURE
NEGATIVE;

NO COVID DIAGNOSTIC TEST
PERFORMED

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: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

AEID

Adverse event

WORSENING ANXIETY

Was this a medically-attended AE?

Yes ☒

No ☐

Was this a Solicited Adverse Reaction?

Yes ☐

No ☒

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

Yes ☐

No ☒

Start date (dd MMM yyyy)

15 SEP 2020

Start time (00:00-23:59)

AE start date and time (derived)

Ongoing?

Yes ☐

No ☒

If not Ongoing, end date (dd MMM yyyy)

15 JAN 2021

End time (00:00-23:59)

AE End Date and Time (derived)

Severity

Grade 1/Mild ☐

Grade 2/Moderate ☒

Grade 3/Severe ☐

Grade 4 ☐

Is the adverse event serious?

Yes ☐

No ☒

AE is serious due To (check all that apply)

Death

False

Life threatening

False

Requires inpatient or prolongation of existing Hospitalization

False

Hospital Admission Date (dd MMM yyyy)

Hospital Discharge Date (dd MMM yyyy)

Admitted to ICU?

Yes ☐

No ☐

Unknown ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (3)

Data signed: (b) (4) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Adverse Events

Form: Adverse Events (4)

Data signed: (b) (4) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

AEID	
Adverse event	ATTENTION DEFICIT DISORDER
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)	03 FEB 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input 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) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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 (5)

Data signed: (b) (4) 05 Apr 2021 14:57:39

Generated On: 09 Jun 2021 17:24:56

AEID	
Adverse event	STRESS INCONTINENCE
Was this a medically-attended AE?	Yes <input checked="" type="radio"/> No <input type="radio"/>
Was this a Solicited Adverse Reaction?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Is this event a confirmed diagnosis of Symptomatic Covid-19?	Yes <input type="radio"/> No <input checked="" type="radio"/>
Start date (dd MMM yyyy)	01 MAR 2021
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input checked="" type="radio"/> Grade 2/Moderate <input 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 (5)

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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 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	True
Concomitant Medication	False
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input checked="" type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
<hr/>	
Narrative <hr/>	
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)	<hr/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

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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) 05 Apr 2021 14:57:40

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Name of Medication LISINOPRIL

Prophylaxis Yes ☐
No ☒

Indication HTN

Dose per administration 10

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 05 Apr 2021 14:57:40

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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 type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	29 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 (2)

Data signed: (b) (4) 05 Apr 2021 14:57:40

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Name of Medication ATROVASTATIN

Prophylaxis Yes ☐
No ☒

Indication HLD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication GLIMEPIRIDE

Prophylaxis Yes ☐
No ☒

Indication T2DM

Dose per administration 2

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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) 05 Apr 2021 14:57:40

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Name of Medication ESTRADIOL

Prophylaxis Yes ☐
No ☒

Indication POST-MENOPAUSE

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 (4)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication OMEPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 40

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

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 (6)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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 2014	
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 (7)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication MCLIZINE

Prophylaxis Yes ☐
No ☒

Indication VERTIGO

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 (7)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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 2015	
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 (8)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication FAMCICLOVIR

Prophylaxis Yes ☐
No ☒

Indication FEVER BLISTERS

Dose per administration 250

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) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication MIDODRINE

Prophylaxis Yes ☐
No ☒

Indication DYSAUTONOMIA

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) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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 2015	
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 (10)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication JANUVIA

Prophylaxis Yes ☐
No ☒

Indication T2DM

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 (10)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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 (11)

Data signed: (b) (4) 05 Apr 2021 14:57:40

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Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication GENERAL SUPPLEMENT

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 (11)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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"/>

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication LYRICA

Prophylaxis Yes ☐
No ☒

Indication DYSAUTONOMIA

Dose per administration 300

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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 2008
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) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication INVOCANA

Prophylaxis Yes ☐
No ☒

Indication DMT2

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 (13)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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 type="radio"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN	UNK 2020
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	29 DEC 2020	
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 (14)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN
"SOLICITED EVENT"

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Data signed: (b) (4) 05 Apr 2021 14:57:40

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

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication MUCINEX COUGH SYRUP

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION AE

Dose per administration UNK

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

If dose unit is Other, specify NONE

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 Q6HR / PRN

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		02 OCT 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 (16)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication ADVIL

Prophylaxis Yes ☐
No ☒

Indication UPPER RESPIRATORY
INFECTION AE

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	29 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		24 OCT 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 (17)

Data signed: (b) (4) 05 Apr 2021 14:57:40

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Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS- LEFT HAND

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	24 NOV 2020	
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 (18)

Data signed: (b) (4) 05 Apr 2021 14:57:40

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Name of Medication METRONIDAZOLE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS - LEFT HAND

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

EVERY EIGHT HOURS

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	24 NOV 2020	
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) _____		
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 (19)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS - LEFT HAND

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	24 NOV 2020	
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)	3	
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 (20)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS - LEFT HAND5

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

EVERY FOUR HOURS AS
NEEDED

Route of administration Oral ☒
Topical ☐
Subcutaneous ☐
Transdermal ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 05 Apr 2021 14:57:40

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	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)	24 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		29 NOV 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 (21)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS (L) HAND

Dose per administration 1.25

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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Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802 <input type="checkbox"/> 803 <input type="checkbox"/> 804 <input checked="" type="checkbox"/>	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication JARDIANCE

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

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 (22)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		30 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"/>

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication DOXYCYCLINE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

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 (23)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	21 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	22 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	2	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication NARCO

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

Dose per administration 5/325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	21 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 NOV 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 (25)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication BACITRACIN-POLYMXIN B

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	21 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 NOV 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 (26)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication IBUPROFEN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

Dose per administration 800

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	21 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 NOV 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 (27)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

Dose per administration 650

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

If dose unit is Other, specify

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

If frequency is Other, specify

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) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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 checked="" 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)	21 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		21 NOV 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 (28)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication TDAP

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS FROM CAT BITE

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 (28)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	21 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	21 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	_____	
Interval Dosage Unit Number (derived)	_____	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication MEROPENEM

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
Separate Dosage Number (derived)	3	
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 (30)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication LIDOCAINE (1%)

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

Dose per administration 1

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

If dose unit is Other, specify PATCH

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 (30)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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 checked="" type="checkbox"/>
If route of administration is Other, specify	TRANSDERMAL	
Start date (dd MMM yyyy)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	23 NOV 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 (31)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication BUSPIRONE

Prophylaxis Yes ☐
No ☒

Indication WORSENING ANXIETY

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 (31)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	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 (32)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication FLUOXETINE

Prophylaxis Yes ☐
No ☒

Indication WORSENING ANXIETY

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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EAB) (1725)

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		15 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication INSULIN ASPART

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 0-12

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 NOV 2020	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication INSULIN ASPART

Prophylaxis Yes ☐
No ☒

Indication TYPE 2 DIABETES

Dose per administration 0-6

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)

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	24 NOV 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"/>	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication CLINDAMYCIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

Dose per administration 600

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy) 22 NOV 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) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication OXYCODONE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

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 (36)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)		22 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 24 NOV 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 (37)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication DILAUEDE

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes <input type="checkbox"/>	
	No <input checked="" type="checkbox"/>	
If not Ongoing, End date (dd MMM yyyy)	23 NOV 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 (38)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication TUMS

Prophylaxis Yes ☐
No ☒

Indication GERD

Dose per administration 1000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)		23 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 23 NOV 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 (39)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication SENOKOT

Prophylaxis Yes ☒
No ☐

Indication PREVENTION OF
CONSTIPATION AS SIDE
EFFECT TO MEDS GIVEN IN
HOSPITAL

Dose per administration 8.6

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	Transdermal	<input type="checkbox"/>
	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)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 NOV 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 (40)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication HEPARIN (5000 UNITS/ML)

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	22 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	24 NOV 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 (41)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication LEVOFLOXACIN

Prophylaxis Yes ☐
No ☒

Indication CELLULITIS LEFT HAND

Dose per administration 750

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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)	23 NOV 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		23 NOV 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"/>

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication LIDEX 0.05%

Prophylaxis Yes ☐
No ☒

Indication ECZEMA

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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 2016	
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 (43)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication SCOPOLAMINE

Prophylaxis Yes ☐
No ☒

Indication DYSAUTONOMIA

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)

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	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 2017	
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"/>

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication DICLOFENAC GEL 1%

Prophylaxis Yes ☐
No ☒

Indication CHRONIC LOW BACK PAIN

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2018	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

Name of Medication ADDERALL

Prophylaxis Yes ☐
No ☒

Indication ATTENTION DEFICIT DISORDER

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003

EAB) (1725)

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US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 05 Apr 2021 14:57:40

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 05 Apr 2021 14:57:45

Generated On: 09 Jun 2021 17:24:56

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
23 NOV 2020	WOUND DEBRIDEMENT OF LEFT HAND	Adverse Event	
21 NOV 2020	X-RAY LEFT WRITS	Adverse Event	
22 NOV 2020	BAMP	Adverse Event	
22 NOV 2020	CBC	Adverse Event	
22 NOV 2020	C-REACTIVE PROTEIN	Adverse Event	
22 NOV 2020	LACTATE	Adverse Event	
23 NOV 2020	CBC	Adverse Event	
22 NOV 2020	BLOOD CULTURE	Adverse Event	
24 NOV 2020	HBAIC	Adverse Event	

US3412013

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:24:56

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

US3412013

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:24:56

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 ☐

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	24/NOV/2020 08:03
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

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	30/NOV/2020 15:06
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	02/DEC/2020 14:32
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

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	07/DEC/2020 20:45
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

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	23/DEC/2020 08:23
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.	True

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	04/JAN/2021 18:33
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

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	07/JAN/2021 15:09
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (8)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	17/FEB/2021 11:35
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

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (9)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	03/MAR/2021 09:01
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

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (10)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	04/MAR/2021 14:20
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

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (11)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	
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.	False

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (12)

Data signed: (b) (4) 05 Apr 2021 14:58:00

Generated On: 09 Jun 2021 17:24:56

SAEID	USA-US061-2020-MRNA-1273-P301000014
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input type="radio"/> No <input checked="" type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	GREGORY
Investigator's Last Name	GOTTSCHLICH
Site Address: Street	4260 GLENDALE MILFORD ROAD
Site Address: City	CINCINNATI
Site Address: State	
Site Address: Postal Code	45242
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	11
Date of submission (Pre-filled from custom function)	16/MAR/2021 12:48
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

US3412013 (Prod: New Horizons Clinical Research)

US3412013

Form: Participant Creation

Generated On: 09 Jun 2021 17:24:56

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:19
User entered 'US3412013'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:44:19

US3412013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:00:42
User entered 'Yes (Y)'	Steven Anderson (b) (4)	29 Jul 2020 16:46:14

US3412013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:00:42
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:44:20

US3412013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:00:42
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:46:14

US3412013

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'SCRN'	System	29 Jul 2020 16:46:14

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered (b) (6) 1962'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:44:21

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '58'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'YEARS'	System	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '58'	System	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

Sex

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered 'Female (F)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered 'l'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

[If race is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered empty.	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

Unknown

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:24:56

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:35
User entered '0'	Steven Anderson (b) (4)	29 Jul 2020 16:46:42

US3412013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:56

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:01:43
User entered '29 Jul 2020'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jul 2020'	System	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '2020'	System	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:56

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered 'Amendment 1 (1)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:56

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered empty.	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:56

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered empty.	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:56

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered 'No (N)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:07

US3412013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:56

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:01:48
User entered empty.	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 15:44:20

US3412013

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:24:56

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'I'	System	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:04:35
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:24:56

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:04:51
User entered 'Yes (Y)'		04 Aug 2020 16:00:46

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:05:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Lipid metabolism disorders, HLT: Hyperlipidaemias NEC, PT: Hyperlipidaemia, LLT: Hyperlipidemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 16:08:07
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 16:08:07
Data point term sent to Coder	System	04 Aug 2020 16:07:19
User entered 'Hyperlipidemia'	(b) (4), (b) (6)	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2010'		04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'		04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.		04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jan 2010'	System	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '2010'	System	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 16:07:06

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:05:46
User coded data point as SOC: Vascular disorders, HLGT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 16:08:07
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 16:08:07
Data point term sent to Coder	System	04 Aug 2020 16:07:19
User entered 'Hypertension'	(b) (4), (b) (6)	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2010'		04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'		04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.		04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jan 2010'	System	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '2010'	System	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 16:07:19

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:05:46
User coded data point as SOC: Gastrointestinal disorders, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastroesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:18:09
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 19:18:09
Data point term sent to Coder	System	04 Aug 2020 19:17:29
User entered 'GERD'	(b) (4), (b) (6)	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2010'		04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'		04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.		04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jan 2010'	System	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '2010'	System	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:17:10

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
User closed query 'Please confirm' (Site from CRA).	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:49:38
Query 'Please confirm' answered with 'confirming' (Site from CRA).	Jacob sekinger (b) (4)	03 Nov 2020 18:11:37
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:44:52
User opened query 'Please confirm' (Site from CRA).		03 Nov 2020 17:43:25
DataPoint Un-verified.		03 Nov 2020 17:43:17
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: Low back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 09:27:41
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Oct 2020 09:27:41
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
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: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:20:00
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 19:20:00
Data point term sent to Coder	System	04 Aug 2020 19:18:30
User entered 'Chronic Lower Back Pain'	(b) (4), (b) (6)	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2007'		04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'		04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.		04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jan 2007'	System	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '2007'	System	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:17:31

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 15:10:14
User closed query 'Please review source and confirm - Type II diabetes?' (Site from CRA).		28 Sep 2020 15:10:11
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 II diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 15:52:38
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 15:52:38
Data point term sent to Coder	System	10 Sep 2020 15:51:59
Query 'Please review source and confirm - Type II diabetes?' answered with 'YES' (Site from CRA).	Mylene Asmar-Rios	10 Sep 2020 15:51:56
Coding entries removed.	(b) (4)	
	Mylene Asmar-Rios	10 Sep 2020 15:51:14
	(b) (4)	
User entered 'DIABETES TYPE II' reason for change: Data Entry Error	Mylene Asmar-Rios	10 Sep 2020 15:51:14
DataPoint Un-verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:07:16
User opened query 'Please review source and confirm - Type II diabetes?' (Site from CRA).		25 Aug 2020 14:07:13
DataPoint Verified.		25 Aug 2020 14:05:46
User coded data point as SOC: Metabolism and nutrition disorders, HLGT: Glucose metabolism disorders (incl diabetes mellitus), HLT: Diabetes mellitus (incl subtypes), PT: Type 1 diabetes mellitus, LLT: Type 1 diabetes mellitus - version MedDRA\23.0.	Coder Import (b) (4)	04 Aug 2020 19:20:02
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	04 Aug 2020 19:20:02
Data point term sent to Coder	System	04 Aug 2020 19:19:32
User entered 'Diabetes Type 1'	(b) (4), (b) (6)	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2005'		04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'		04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.		04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jan 2005'	System	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '2005'	System	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:18:32

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:05:46
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:20:02
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 19:20:02
Data point term sent to Coder	System	04 Aug 2020 19:19:34
User entered 'Anxiety'	(b) (4), (b) (6)	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2010'		04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'		04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.		04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jan 2010'	System	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '2010'	System	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:18:45

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:05:46
User coded data point as SOC: Ear and labyrinth disorders, HLGT: Inner ear and VIIIth cranial nerve disorders, HLT: Inner ear signs and symptoms, PT: Vertigo, LLT: Vertigo - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 19:20:02
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 19:20:02
Data point term sent to Coder	System	04 Aug 2020 19:19:31
User entered 'Vertigo'	(b) (4), (b) (6)	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2015'		04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'		04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.		04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jan 2015'	System	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '2015'	System	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:18:59

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:05:46
User coded data point as SOC: Infections and infestations, HLGT: Viral infectious disorders, HLT: Herpes viral infections, PT: Oral herpes, LLT: Fever blister - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	04 Aug 2020 23:00:07
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 23:00:07
Data point term sent to Coder	System	04 Aug 2020 19:19:34
User entered 'Fever Blisters'	(b) (4), (b) (6)	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Un UNK 1965'		04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'		04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.		04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jan 1965'	System	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '1965'	System	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:19:14

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:56

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 15:10:49
User closed query 'Please correct spelling Dysautonomia' (Site from CRA).		28 Sep 2020 15:10:46
User coded data point as SOC: Nervous system disorders, HLG: Neuromuscular disorders, HLT: Autonomic nervous system disorders, PT: Autonomic nervous system imbalance, LLT: Dysautonomia - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 15:54:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	10 Sep 2020 15:54:55
Query 'Please correct spelling Dysautonomia' answered with 'dysautonomia' (Site from CRA).	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:53:13
Data point term sent to Coder	System	10 Sep 2020 15:53:05
Data point term sent to Coder	System	10 Sep 2020 15:53:05
User closed query 'DM-Coding: Please update the term DYSACRINOMIA by providing further details for a more specific meaning/diagnosis.' (Site from System).	System	10 Sep 2020 15:53:05
Query 'DM-Coding: Please update the term DYSACRINOMIA by providing further details for a more specific meaning/diagnosis.' answered with 'dysautonomia' (Site from System).	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:53:05
User entered 'dysautonomia' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:52:58
DataPoint Un-verified.	(b) (4), (b) (6)	25 Aug 2020 14:16:55
User opened query 'Please correct spelling Dysautonomia' (Site from CRA).		25 Aug 2020 14:15:48
DataPoint Verified.		25 Aug 2020 14:05:46
User opened query 'DM-Coding: Please update the term DYSACRINOMIA by providing further details for a more specific meaning/diagnosis.' (Site from System).	Coder Import (b) (4)	14 Aug 2020 06:54:09
Data point term sent to Coder	System	04 Aug 2020 19:19:34
User entered 'Dysacrinomia'	(b) (4), (b) (6)	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:44:40
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	29 Sep 2020 21:24:02
User entered 'UN UNK 2008' reason for change:	Mylene Asmar-Rios	29 Sep 2020 21:24:02
Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'UN UNK 2015'		04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered 'Yes (Y)'		04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:05:46
User entered '0'		04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jan 2008'	System	29 Sep 2020 21:24:02
User entered 'Jan 2015'	System	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '2008'	System	29 Sep 2020 21:24:02
User entered '2015'	System	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	04 Aug 2020 19:19:31

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:44:52
User coded data point as SOC: Social circumstances, HLGT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:42:53
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	08 Oct 2020 22:42:53
Data point term sent to Coder	System	08 Oct 2020 14:58:58
User entered 'post menopausal'	Jacob sekinger (b) (4) (b) (4)	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:44:52
User entered 'un UNK 2008'	Jacob sekinger (b) (4) (b) (4)	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:44:52
User entered '0'	Jacob sekinger (b) (4) (b) (4)	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:44:52
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:44:52
User entered empty.	Jacob sekinger (b) (4) (b) (4)	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:44:52
User entered '0'	Jacob sekinger (b) (4) (b) (4)	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jan 2008'	System	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '2008'	System	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	08 Oct 2020 14:58:08

US3412013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:56

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User coded data point as SOC: Skin and subcutaneous tissue disorders, HLGT: Epidermal and dermal conditions, HLT: Dermatitis and eczema, PT: Eczema, LLT: Eczema - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:33:40
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	07 Apr 2021 18:33:40
Data point term sent to Coder	System	07 Apr 2021 18:33:01
Datapoint queued for coding (5337921).	System	07 Apr 2021 18:32:38
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 19:52:59
User signature succeeded.	Richard Powell (b) (4) (b) (4)	10 Mar 2021 19:25:52
User entered 'ECZeMA' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 15:11:16
Data point term sent to Coder	System	03 Mar 2021 15:11:11
User entered 'eczama'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 15:11:08

US3412013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
DataPoint Verified.		13 Mar 2021 19:53:02
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:52
User entered 'un UNK 1995'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 15:11:08

US3412013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 19:53:04
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:52
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 15:11:08

US3412013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:56

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 19:53:08
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:52
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	03 Mar 2021 15:11:08

US3412013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 19:53:12
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:52
User entered empty.	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 15:11:08

US3412013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:56

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
DataPoint Verified.		13 Mar 2021 19:53:14
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:52
User entered '0'	(b) (4) Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 15:11:08

US3412013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'Jan 1995'	System	03 Mar 2021 15:11:08

US3412013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '1995'	System	03 Mar 2021 15:11:08

US3412013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	03 Mar 2021 15:11:08

US3412013

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered empty.	System	03 Mar 2021 15:11:08

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:17:22
User entered 'Yes (Y)'		04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:17:24
User entered '29 Jul 2020'		04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:17:31
User entered '12:05'		04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered '29 Jul 2020 12:05'	System	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:17:42
User entered '167.5' cm		04 Aug 2020 19:24:53
DataPoint set to visible.	System	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:17:44
User entered '87.6' kg		04 Aug 2020 19:24:53
DataPoint set to visible.	System	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
Amendment Manager: User entered '31.22299'	System	16 Sep 2020 23:38:05
User entered '31.2'	System	04 Aug 2020 19:24:53
DataPoint set to visible.	System	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'kg/m2'	System	04 Aug 2020 19:24:53
DataPoint set to visible.	System	29 Jul 2020 16:47:14

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:48:10
User entered '36.8' C	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:45:36
User closed query 'Data is required. Please provide.' (Site from System).		20 Aug 2020 04:22:55
Query 'Data is required. Please provide.' answered with 'ND' (Site from System).	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:48:19
User opened query 'Data is required. Please provide.' (Site from System).	System	19 Aug 2020 16:48:10
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:48:10
User entered 'Oral (Oral)'	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered empty.		04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:48:10
User entered '82'	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'bpm'	System	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:48:10
User entered '16'	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'breaths/min'	System	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:48:10
User entered '128'	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'mmHg'	System	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:45:36
User entered missing code ND - Not Done; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:48:10
User entered '76'	(b) (4), (b) (6)	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User entered 'mmHg'	System	04 Aug 2020 19:24:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53

US3412013

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53

US3412013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:18:04
User entered 'Yes (Y)'		04 Aug 2020 19:25:08

US3412013

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
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 13:35:12
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).		26 Aug 2020 15:55:55
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:18:04
User entered '29 Jul 2020'		04 Aug 2020 19:25:08

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered '29 Jul 2020'		04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:56

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered 'No (N)'		04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:56

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
User closed query 'Per CDML Response noted. However, the condition is not recorded on the Medical History CRF. Please update. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 12:29:25
Query 'Per CDML Response noted. However, the condition is not recorded on the Medical History CRF. Please update. ' answered with 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	08 Oct 2020 14:57:32
User opened query 'Per CDML Response noted. However, the condition is not recorded on the Medical History CRF. Please update. ' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 19:08:23
User closed query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).		07 Oct 2020 19:08:23
Query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' answered with 'ok' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Oct 2020 13:26:22
User opened query 'Per DM CLR: Please review this condition as this is not recorded in MH ecrf. Record this condition in MH ecrf as appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Oct 2020 07:33:39
DataPoint Verified.		25 Aug 2020 14:19:06
User entered 'Post-menopausal (POST-MENOPAUSAL)'		04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:56

[If Partner medically sterile or Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered empty.		04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:56

If Surgically sterile, date of surgery (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered empty.		04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:56

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered '0'		04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:56

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered 'un UNK 2008'		04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:24:56

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:06
User entered '0'		04 Aug 2020 19:25:44

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:20
User entered 'No (N)'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:22
User entered 'No (N)'		04 Aug 2020 19:26:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:24
User entered 'No (N)'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:30
User entered 'No (N)'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

[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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:32
User entered 'No (N)'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

[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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:34
User entered 'No (N)'		04 Aug 2020 19:26:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:36
User entered 'No (N)'		04 Aug 2020 19:26:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:42
User entered 'No (N)'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

[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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:44
User entered 'No (N)'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:46
User entered 'No (N)'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:19:58
User entered 'No (N)'		04 Aug 2020 19:26:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

Other

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered 'No (N)'		04 Aug 2020 19:26:26

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Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered empty.		04 Aug 2020 19:26:26

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Folder: Screening

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Generated On: 09 Jun 2021 17:24:56

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
User entered '0'	(b) (4) (b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered '0'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered '0'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered 'I'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered '0'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered '0'		04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	02 Oct 2020 12:14:04
User entered '0'	(b) (4)	
	(b) (4), (b) (6)	04 Aug 2020 19:26:26

US3412013

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:24:56

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Apr 2021 10:32:53
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:45:23
DataPoint Un-verified.	Steven Anderson (b) (4)	02 Oct 2020 12:14:04
User entered 'Socializes, shared apartment entrance, and lives in high risk county' reason for change: Data Entry Error	(b) (4) Steven Anderson (b) (4)	02 Oct 2020 12:14:04
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:20:09
User entered empty.		04 Aug 2020 19:26:26

US3412013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:21:01
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:31

US3412013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:21:01
User entered '29 Jul 2020'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:31

US3412013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[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 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:21:01
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:31

US3412013

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'VISIT1'	System	29 Jul 2020 16:47:31

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:29:36
User entered '29 JUL 2020'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:44:34

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:56

What was the participant's randomization number?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:29:36
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	21 Aug 2020 01:14:30
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 01:14:30
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	29 Jul 2020 16:44:34
User entered '142255' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:44:34

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:56

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
User closed query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	(b) (4)	
	System	10 Sep 2020 15:57:11
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:36
User opened query 'Cohort = at risk; however, there are no risk items recorded as Yes. Please review and reconcile.' (Site from System).	System	29 Jul 2020 16:47:49
User entered '>=18 and <65 years and at risk (2)'	RWS_ENDPOINT ENDPOINT (b) (4)	29 Jul 2020 16:44:34

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:56

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 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:29:36
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:49

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:56

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 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:29:36
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:49

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:29:36
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:49

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:56

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	28 Sep 2020 15:11:25
User closed query 'Subject has Type II diabetes per source - please confirm and correct response to YES' (Site from CRA).		28 Sep 2020 15:11:19
Query 'Subject has Type II diabetes per source - please confirm and correct response to YES' answered with 'YES' (Site from CRA).	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:57:18
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:57:11
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:57:11
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:36
User opened query 'Subject has Type II diabetes per source - please confirm and correct response to YES' (Site from CRA).		25 Aug 2020 14:29:22
User entered 'No (N)'	Steven Anderson (b) (4)	29 Jul 2020 16:47:49

US3412013

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:24:56

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:29:36
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 16:47:49

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:54
User entered missing code ND - Not Done.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:56
User entered missing code ND - Not Done.		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:54
User entered missing code ND - Not Done.		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:56
User entered missing code ND - Not Done.		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User accepted default value 'Pre-Dose (PREDOSE)'		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:53:09
User entered 'No (N)'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '29 Jul 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:53:09
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '12:05' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:53:09
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered '29 Jul 2020 12:05'	System	19 Aug 2020 16:53:09
User entered empty.	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '36.8' C reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:53:09
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:53:09
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered empty.		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '82' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:53:09
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'bpm'	System	19 Aug 2020 16:53:09
User entered empty.	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '16' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:53:09
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'breaths/min'	System	19 Aug 2020 16:53:09
User entered empty.	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '128' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:53:09
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'mmHg'	System	19 Aug 2020 16:53:09
User entered empty.	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '76' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:53:09
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'mmHg'	System	19 Aug 2020 16:53:09
User entered empty.	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:56

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:54
User entered missing code ND - Not Done.		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:24:56

[Weight](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:29:56
User entered missing code ND - Not Done.		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User accepted default value 'Post-Dose (POSTDOSE)'		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered 'Yes (Y)'		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '29 Jul 2020'		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User closed query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		17 Aug 2020 16:00:11
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 are > 30 min' (Site from System).		04 Aug 2020 19:22:02
User opened query 'Post-dose vital signs time is prior System to or less than 60 minutes after the Dose Time. Please review and reconcile.' (Site from System).		04 Aug 2020 19:21:35
User entered '13:35'	(b) (4), (b) (6)	04 Aug 2020 19:21:35

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered '29 Jul 2020 13:35'	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:58
User entered '97.3' F reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:59:59
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:57:44
User entered '97.8' F reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:57:44
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '97.3' F		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered 'Oral (Oral)'		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered empty.	(b) (4), (b) (6)	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:58
User entered '75' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:59:59
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:58:16
User entered '84' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:58:16
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '75'		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'bpm'	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '18'		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'breaths/min'	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:58
User entered '125' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:59:59
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:58:40
User entered '128' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:58:40
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '125'		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'mmHg'	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:46:58
User entered '70' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:59:59
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:58:40
User entered '72' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 15:58:40
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:36:47
User entered '70'		04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'mmHg'	System	04 Aug 2020 19:21:35

US3412013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:04
User entered 'No (N)'		04 Aug 2020 19:22:19

US3412013

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:04
User entered empty.		04 Aug 2020 19:22:19

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered empty.	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

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 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered empty.	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'MRNA-1273 OR PLACEBO'	System	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered '29 Jul 2020'	Steven Anderson (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered '13:00'	Steven Anderson (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered '29 Jul 2020 13:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:37:14
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4) (b) (4)	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
DataPoint Verified.		25 Aug 2020 14:37:14
User entered 'ONCE'	System	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'INTRAMUSCULAR'	System	29 Jul 2020 17:03:20

US3412013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:56
User entered 'Yes (Y)'		04 Aug 2020 19:23:23

US3412013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:56
User entered '29 Jul 2020'		04 Aug 2020 19:23:23

US3412013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:37:56
User entered '12:25'		04 Aug 2020 19:23:23

US3412013

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered '29 Jul 2020 12:25'	System	04 Aug 2020 19:23:23

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:24:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:38:05
User entered '29 Jul 2020'		04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'		04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:38:05
User entered 'Yes (Y)'		04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:38:05
User entered '12:37'		04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered '29 Jul 2020 12:37'	System	04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'		04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:38:05
User entered 'No (N)'		04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:38:05
User entered empty.		04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered empty.	System	04 Aug 2020 19:23:12

US3412013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:38:56
User entered 'Yes (Y)'		04 Aug 2020 19:22:26

US3412013

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'I'	System	04 Aug 2020 19:22:26

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:38:55', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4e2c5d12-1a29-4464-b268-dcb9b9c3b432'	System	29 Jul 2020 17:39:41
User entered 'Yes (Y)'	System	29 Jul 2020 17:39:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:39:01', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4e2c5d12-1a29-4464-b268-dcb9b9c3b432'	System	29 Jul 2020 17:39:41
User entered '97.3'	System	29 Jul 2020 17:39:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:39:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4e2c5d12-1a29-4464-b268-dcb9b9c3b432'	System	29 Jul 2020 17:39:41
User entered 'No (N)'	System	29 Jul 2020 17:39:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:39:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4e2c5d12-1a29-4464-b268-dcb9b9c3b432'	System	29 Jul 2020 17:39:41
User entered '29 Jul 2020 13:39'	System	29 Jul 2020 17:39:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Jul 2020 13:20'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Jul 2020 15:50'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:05:06', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '39e31811-8381-41e0-af14-c20f7d5b3a5c'	System	30 Jul 2020 00:05:55
User entered 'Yes (Y)'	System	30 Jul 2020 00:05:55

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:05:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '39e31811-8381-41e0-af14-c20f7d5b3a5c'	System	30 Jul 2020 00:05:55
User entered '98.2'	System	30 Jul 2020 00:05:55

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:05:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '39e31811-8381-41e0-af14-c20f7d5b3a5c'	System	30 Jul 2020 00:05:55
User entered 'No (N)'	System	30 Jul 2020 00:05:55

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:05:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '39e31811-8381-41e0-af14-c20f7d5b3a5c'	System	30 Jul 2020 00:05:55
User entered '29 Jul 2020 20:05'	System	30 Jul 2020 00:05:55

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Jul 2020 16:45'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 2'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:36:43', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f66c9578-0201-4d3d-b863-0e88ef402d56'	System	30 Jul 2020 16:37:18
User entered 'Yes (Y)'	System	30 Jul 2020 16:37:18

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:36:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f66c9578-0201-4d3d-b863-0e88ef402d56'	System	30 Jul 2020 16:37:18
User entered '97.3'	System	30 Jul 2020 16:37:18

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:36:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f66c9578-0201-4d3d-b863-0e88ef402d56'	System	30 Jul 2020 16:37:18
User entered 'No (N)'	System	30 Jul 2020 16:37:18

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:37:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f66c9578-0201-4d3d-b863-0e88ef402d56'	System	30 Jul 2020 16:37:18
User entered '30 Jul 2020 12:37'	System	30 Jul 2020 16:37:18

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 3'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:55:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '82c3d665-24e0-4b63-a4fb-92a398bdf4e0'	System	31 Jul 2020 16:55:52
User entered 'Yes (Y)'	System	31 Jul 2020 16:55:52

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:55:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '82c3d665-24e0-4b63-a4fb-92a398bdf4e0'	System	31 Jul 2020 16:55:52
User entered '98.1'	System	31 Jul 2020 16:55:52

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:55:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '82c3d665-24e0-4b63-a4fb-92a398bdf4e0'	System	31 Jul 2020 16:55:52
User entered 'No (N)'	System	31 Jul 2020 16:55:52

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:55:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '82c3d665-24e0-4b63-a4fb-92a398bdf4e0'	System	31 Jul 2020 16:55:52
User entered '31 Jul 2020 12:55'	System	31 Jul 2020 16:55:52

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 4'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:30', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3db054d6-4b4a-44c9-8cd2-edcc1716e86e'	System	01 Aug 2020 22:25:34
User entered 'Yes (Y)'	System	01 Aug 2020 22:25:34

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3db054d6-4b4a-44c9-8cd2-edcc1716e86e'	System	01 Aug 2020 22:25:34
User entered '97.8'	System	01 Aug 2020 22:25:34

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:23', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3db054d6-4b4a-44c9-8cd2-edcc1716e86e'	System	01 Aug 2020 22:25:34
User entered 'No (N)'	System	01 Aug 2020 22:25:34

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:45', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3db054d6-4b4a-44c9-8cd2-edcc1716e86e'	System	01 Aug 2020 22:25:34
User entered '01 Aug 2020 18:24'	System	01 Aug 2020 22:25:34

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 5'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:02:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e9ed12f6-fddf-4d15-8713-71d859e54c84'	System	02 Aug 2020 17:03:10
User entered 'Yes (Y)'	System	02 Aug 2020 17:03:10

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:02:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e9ed12f6-fddf-4d15-8713-71d859e54c84'	System	02 Aug 2020 17:03:10
User entered '97.6'	System	02 Aug 2020 17:03:10

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:02:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e9ed12f6-fddf-4d15-8713-71d859e54c84'	System	02 Aug 2020 17:03:10
User entered 'No (N)'	System	02 Aug 2020 17:03:10

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e9ed12f6-fddf-4d15-8713-71d859e54c84'	System	02 Aug 2020 17:03:10
User entered '02 Aug 2020 13:03'	System	02 Aug 2020 17:03:10

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 6'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T12:37:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd31ea303-1166-447c-8ed4-36aa309e3cfc'	System	03 Aug 2020 16:38:41
User entered 'Yes (Y)'	System	03 Aug 2020 16:38:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T12:37:55', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd31ea303-1166-447c-8ed4-36aa309e3cfc'	System	03 Aug 2020 16:38:41
User entered '97.8'	System	03 Aug 2020 16:38:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T12:37:59', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd31ea303-1166-447c-8ed4-36aa309e3cfc'	System	03 Aug 2020 16:38:41
User entered 'No (N)'	System	03 Aug 2020 16:38:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T12:38:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd31ea303-1166-447c-8ed4-36aa309e3cfc'	System	03 Aug 2020 16:38:41
User entered '03 Aug 2020 12:38'	System	03 Aug 2020 16:38:41

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 7'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:29:57', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '882b1bff-b13e-4767-bb7b-510910f79397'	System	05 Aug 2020 15:30:19
User entered 'Yes (Y)'	System	05 Aug 2020 15:30:19

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:03', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '882b1bff-b13e-4767-bb7b-510910f79397'	System	05 Aug 2020 15:30:19
User entered '97.7'	System	05 Aug 2020 15:30:19

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:06', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '882b1bff-b13e-4767-bb7b-510910f79397'	System	05 Aug 2020 15:30:19
User entered 'No (N)'	System	05 Aug 2020 15:30:19

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:11', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '882b1bff-b13e-4767-bb7b-510910f79397'	System	05 Aug 2020 15:30:19
User entered '05 Aug 2020 11:30'	System	05 Aug 2020 15:30:19

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:41:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0bc02c18-93d4-4b3d-bf45-73b05f84b419'	System	29 Jul 2020 17:42:34
User entered 'Does not interfere with activity (2)'	System	29 Jul 2020 17:42:34

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:41:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0bc02c18-93d4-4b3d-bf45-73b05f84b419'	System	29 Jul 2020 17:42:34
User entered 'No (N)'	System	29 Jul 2020 17:42:34

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:41:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0bc02c18-93d4-4b3d-bf45-73b05f84b419'	System	29 Jul 2020 17:42:34
User entered 'No (N)'	System	29 Jul 2020 17:42:34

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:42:18', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0bc02c18-93d4-4b3d-bf45-73b05f84b419'	System	29 Jul 2020 17:42:34
User entered 'Does not interfere with activity (2)'	System	29 Jul 2020 17:42:34

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:42:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0bc02c18-93d4-4b3d-bf45-73b05f84b419'	System	29 Jul 2020 17:42:34
User entered '29 Jul 2020 13:42'	System	29 Jul 2020 17:42:34

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Jul 2020 13:20'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Jul 2020 15:50'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:02:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '809addc8-7b98-477b-a86e-5bbf70ea7890'	System	30 Jul 2020 00:03:18
User entered 'Does not interfere with activity (2)'	System	30 Jul 2020 00:03:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:02:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '809addc8-7b98-477b-a86e-5bbf70ea7890'	System	30 Jul 2020 00:03:18
User entered 'No (N)'	System	30 Jul 2020 00:03:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:02:59', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '809addc8-7b98-477b-a86e-5bbf70ea7890'	System	30 Jul 2020 00:03:18
User entered 'No (N)'	System	30 Jul 2020 00:03:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:03', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '809addc8-7b98-477b-a86e-5bbf70ea7890'	System	30 Jul 2020 00:03:18
User entered 'None (1)'	System	30 Jul 2020 00:03:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '809addc8-7b98-477b-a86e-5bbf70ea7890'	System	30 Jul 2020 00:03:18
User entered '29 Jul 2020 20:03'	System	30 Jul 2020 00:03:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Jul 2020 16:45'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 2'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:37:43', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd775eaf6-a22c-446c-9bb8-73aa29698553'	System	30 Jul 2020 16:38:11
User entered 'Does not interfere with activity (2)'	System	30 Jul 2020 16:38:11

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:37:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd775eaf6-a22c-446c-9bb8-73aa29698553'	System	30 Jul 2020 16:38:11
User entered 'No (N)'	System	30 Jul 2020 16:38:11

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:37:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd775eaf6-a22c-446c-9bb8-73aa29698553'	System	30 Jul 2020 16:38:11
User entered 'No (N)'	System	30 Jul 2020 16:38:11

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:37:57', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd775eaf6-a22c-446c-9bb8-73aa29698553'	System	30 Jul 2020 16:38:11
User entered 'None (1)'	System	30 Jul 2020 16:38:11

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd775eaf6-a22c-446c-9bb8-73aa29698553'	System	30 Jul 2020 16:38:11
User entered '30 Jul 2020 12:38'	System	30 Jul 2020 16:38:11

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 3'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:55:57', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1e2ee076-c617-4ac3-802b-fbad760242af'	System	31 Jul 2020 16:56:18
User entered 'Does not interfere with activity (2)'	System	31 Jul 2020 16:56:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1e2ee076-c617-4ac3-802b-fbad760242af'	System	31 Jul 2020 16:56:18
User entered 'No (N)'	System	31 Jul 2020 16:56:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:03', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1e2ee076-c617-4ac3-802b-fbad760242af'	System	31 Jul 2020 16:56:18
User entered 'No (N)'	System	31 Jul 2020 16:56:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1e2ee076-c617-4ac3-802b-fbad760242af'	System	31 Jul 2020 16:56:18
User entered 'None (1)'	System	31 Jul 2020 16:56:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:13', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1e2ee076-c617-4ac3-802b-fbad760242af'	System	31 Jul 2020 16:56:18
User entered '31 Jul 2020 12:56'	System	31 Jul 2020 16:56:18

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 4'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:50', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '7f26ece9-a9fd-46b2-b792-bf664b470686'	System	01 Aug 2020 22:26:00
User entered 'None (1)'	System	01 Aug 2020 22:26:00

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '7f26ece9-a9fd-46b2-b792-bf664b470686'	System	01 Aug 2020 22:26:00
User entered 'No (N)'	System	01 Aug 2020 22:26:00

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:24:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '7f26ece9-a9fd-46b2-b792-bf664b470686'	System	01 Aug 2020 22:26:00
User entered 'No (N)'	System	01 Aug 2020 22:26:00

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:01', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '7f26ece9-a9fd-46b2-b792-bf664b470686'	System	01 Aug 2020 22:26:00
User entered 'None (1)'	System	01 Aug 2020 22:26:00

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:06', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '7f26ece9-a9fd-46b2-b792-bf664b470686'	System	01 Aug 2020 22:26:00
User entered '01 Aug 2020 18:25'	System	01 Aug 2020 22:26:00

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 5'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:15', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f919fd9a-eae5-4bbd-863c-7de89f57fb91'	System	02 Aug 2020 17:03:38
User entered 'None (1)'	System	02 Aug 2020 17:03:38

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f919fd9a-eae5-4bbd-863c-7de89f57fb91'	System	02 Aug 2020 17:03:38
User entered 'No (N)'	System	02 Aug 2020 17:03:38

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:23', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f919fd9a-eae5-4bbd-863c-7de89f57fb91'	System	02 Aug 2020 17:03:38
User entered 'No (N)'	System	02 Aug 2020 17:03:38

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f919fd9a-eae5-4bbd-863c-7de89f57fb91'	System	02 Aug 2020 17:03:38
User entered 'None (1)'	System	02 Aug 2020 17:03:38

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f919fd9a-eae5-4bbd-863c-7de89f57fb91'	System	02 Aug 2020 17:03:38
User entered '02 Aug 2020 13:03'	System	02 Aug 2020 17:03:38

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 6'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:44:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '062f963d-4203-48f9-86f6-773c6563f72e'	System	03 Aug 2020 18:45:09
User entered 'None (1)'	System	03 Aug 2020 18:45:09

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:44:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '062f963d-4203-48f9-86f6-773c6563f72e'	System	03 Aug 2020 18:45:09
User entered 'No (N)'	System	03 Aug 2020 18:45:09

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:44:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '062f963d-4203-48f9-86f6-773c6563f72e'	System	03 Aug 2020 18:45:09
User entered 'No (N)'	System	03 Aug 2020 18:45:09

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '062f963d-4203-48f9-86f6-773c6563f72e'	System	03 Aug 2020 18:45:09
User entered 'None (1)'	System	03 Aug 2020 18:45:09

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '062f963d-4203-48f9-86f6-773c6563f72e'	System	03 Aug 2020 18:45:09
User entered '03 Aug 2020 14:45'	System	03 Aug 2020 18:45:09

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 7'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fa76671a-7924-4281-9081-5173cc8ad7cb'	System	05 Aug 2020 15:30:36
User entered 'None (1)'	System	05 Aug 2020 15:30:36

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fa76671a-7924-4281-9081-5173cc8ad7cb'	System	05 Aug 2020 15:30:36
User entered 'No (N)'	System	05 Aug 2020 15:30:36

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:23', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fa76671a-7924-4281-9081-5173cc8ad7cb'	System	05 Aug 2020 15:30:36
User entered 'No (N)'	System	05 Aug 2020 15:30:36

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:28', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fa76671a-7924-4281-9081-5173cc8ad7cb'	System	05 Aug 2020 15:30:36
User entered 'None (1)'	System	05 Aug 2020 15:30:36

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fa76671a-7924-4281-9081-5173cc8ad7cb'	System	05 Aug 2020 15:30:36
User entered '05 Aug 2020 11:30'	System	05 Aug 2020 15:30:36

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:16', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:18', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:21', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'None (0)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:28', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered 'No (N)'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T13:43:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '73baa90a-81ae-46d8-83f5-3fe35279ff80'	System	29 Jul 2020 17:43:58
User entered '29 Jul 2020 13:43'	System	29 Jul 2020 17:43:58

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Jul 2020 13:20'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Jul 2020 15:50'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 1, after vaccination (at home)'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:31', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'None (0)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered 'No (N)'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-29T20:03:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'eb697ede-c6b8-423b-ab6b-644ad2b02fa3'	System	30 Jul 2020 00:04:02
User entered '29 Jul 2020 20:03'	System	30 Jul 2020 00:04:02

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Jul 2020 16:45'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 2'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:13', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:16', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'None (0)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered 'No (N)'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-30T12:38:50', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1aedd816-1462-4bf1-99dc-7f1485968e75'	System	30 Jul 2020 16:38:55
User entered '30 Jul 2020 12:38'	System	30 Jul 2020 16:38:55

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Jul 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 3'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:19', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:36', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:47', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'None (0)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:56:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered 'No (N)'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-07-31T12:57:01', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '18f767da-2da5-4a3d-8822-c3c30b5f10a5'	System	31 Jul 2020 16:57:07
User entered '31 Jul 2020 12:57'	System	31 Jul 2020 16:57:07

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Jul 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 4'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:13', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:18', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:21', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:25', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'None (0)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered 'No (N)'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-01T18:25:41', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2b819f38-97ea-448b-abd8-c6516e1aad2e'	System	01 Aug 2020 22:26:20
User entered '01 Aug 2020 18:25'	System	01 Aug 2020 22:26:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '02 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 5'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:52', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:55', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:03:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:04:01', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'None (0)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:04:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered 'No (N)'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-02T13:04:12', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '1f2ddf9f-026a-44ce-b379-eef99e13d078'	System	02 Aug 2020 17:04:14
User entered '02 Aug 2020 13:04'	System	02 Aug 2020 17:04:14

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '02 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '03 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 6'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:16', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:23', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:26', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'None (0)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:30', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered 'No (N)'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-03T14:45:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bd1d5769-c9ab-471e-9d41-82200e9ff23d'	System	03 Aug 2020 18:45:40
User entered '03 Aug 2020 14:45'	System	03 Aug 2020 18:45:40

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '03 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '04 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 7'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:47', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:50', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:52', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'None (0)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:55', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered 'No (N)'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-05T11:30:59', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '71a419a2-15f8-4b0d-bb1f-2108eee38bd2'	System	05 Aug 2020 15:31:04
User entered '05 Aug 2020 11:30'	System	05 Aug 2020 15:31:04

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '04 Aug 2020 12:00'	System	29 Jul 2020 17:03:20

US3412013

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '05 Aug 2020 11:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:42
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	05 Aug 2020 22:26:39

US3412013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:42
User entered '05 Aug 2020'	Steven Anderson (b) (4) (b) (4)	05 Aug 2020 22:26:39

US3412013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:42
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4) (b) (4)	05 Aug 2020 22:26:39

US3412013

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:41:42
User entered empty.	Steven Anderson (b) (4) (b) (4)	05 Aug 2020 22:26:39

US3412013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:42:07
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	05 Aug 2020 22:26:44

US3412013

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'I'	System	05 Aug 2020 22:26:44

US3412013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:42:32
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 14:08:21

US3412013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:42:32
User entered '12 Aug 2020'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 14:08:21

US3412013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:42:32
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 14:08:21

US3412013

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:42:32
User entered empty.	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 14:08:21

US3412013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:42:37
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	17 Aug 2020 14:08:30

US3412013

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'I'	System	17 Aug 2020 14:08:30

US3412013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:42:48
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	19 Aug 2020 22:31:12

US3412013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:42:48
User entered '19 Aug 2020'	Steven Anderson (b) (4) (b) (4)	19 Aug 2020 22:31:12

US3412013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:42:48
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4) (b) (4)	19 Aug 2020 22:31:12

US3412013

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:42:48
User entered empty.	Steven Anderson (b) (4) (b) (4)	19 Aug 2020 22:31:12

US3412013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:42:59
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	19 Aug 2020 22:31:18

US3412013

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'I'	System	19 Aug 2020 22:31:18

US3412013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:28:24
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:55:55

US3412013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:28:24
User entered '26 Aug 2020'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:55:55

US3412013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[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 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:28:24
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:55:55

US3412013

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'VISIT2'	System	26 Aug 2020 15:55:55

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45
	(b) (4)	

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:35:58
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:35:59
User entered '26 Aug 2020'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:36:00
User entered '11:06'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered '26 Aug 2020 11:06'	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:36:05
User entered '36.9' C	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:36:08
User entered 'Oral (Oral)'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:36:14
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:36:12
User entered '90'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'bpm'	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:36:16
User entered '18'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'breaths/min'	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:36:18
User entered '115'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'mmHg'	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:36:20
User entered '60'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'mmHg'	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:20
User closed query 'Data is required. Please complete.' (Site from System).	System	10 Sep 2020 16:04:16
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	10 Sep 2020 16:04:16
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:04:16
User opened query 'Data is required. Please complete.' (Site from System).	System	26 Aug 2020 15:56:45
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '26 Aug 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:04:16
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '12:35' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:04:16
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered '26 Aug 2020 12:35'	System	10 Sep 2020 16:04:16
User entered empty.	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '97.8' F reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:04:16
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered 'Oral (Oral)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:04:16
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered empty.	Steven Anderson (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '84' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:04:16
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'bpm'	System	10 Sep 2020 16:04:16
User entered empty.	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '18' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:04:16
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'breaths/min'	System	10 Sep 2020 16:04:16
User entered empty.	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '128' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:04:16
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'mmHg'	System	10 Sep 2020 16:04:16
User entered empty.	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:20
User entered '72' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:04:16
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'mmHg'	System	10 Sep 2020 16:04:16
User entered empty.	System	26 Aug 2020 15:56:45

US3412013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:37:13
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:57:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:37:13
User entered '26 Aug 2020'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:57:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

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 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered empty.	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'MRNA-1273 OR PLACEBO'	System	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered '26 Aug 2020'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered '12:05'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered '26 Aug 2020 12:05'	System	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:37:30
User entered 'ONCE'	System	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:24:56

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'INTRAMUSCULAR'	System	26 Aug 2020 16:09:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:37:54
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:57:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:37:54
User entered '26 Aug 2020'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:57:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:37:54
User entered '11:40'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:57:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered '26 Aug 2020 11:40'	System	26 Aug 2020 15:57:42

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:24:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:47:38
User entered '26 Aug 2020'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:47:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:47:38
User entered '11:49'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered '26 Aug 2020 11:49'	System	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:56

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:47:38
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:47:38
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered empty.	System	10 Sep 2020 16:07:00

US3412013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	09 Sep 2020 15:38:16
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	26 Aug 2020 15:57:47

US3412013

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'I'	System	26 Aug 2020 15:57:47

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:36:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '70db97fc-dc0f-4a11-bb3e-051581546043'	System	26 Aug 2020 16:37:25
User entered 'Yes (Y)'	System	26 Aug 2020 16:37:25

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '70db97fc-dc0f-4a11-bb3e-051581546043'	System	26 Aug 2020 16:37:25
User entered '97.8'	System	26 Aug 2020 16:37:25

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '70db97fc-dc0f-4a11-bb3e-051581546043'	System	26 Aug 2020 16:37:25
User entered 'No (N)'	System	26 Aug 2020 16:37:25

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:21', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '70db97fc-dc0f-4a11-bb3e-051581546043'	System	26 Aug 2020 16:37:25
User entered '26 Aug 2020 12:37'	System	26 Aug 2020 16:37:25

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '26 Aug 2020 12:25'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '26 Aug 2020 14:55'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T18:59:26', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '994f1c89-8080-4c70-b5dd-9e1c92cca37f'	System	26 Aug 2020 22:59:51
User entered 'Yes (Y)'	System	26 Aug 2020 22:59:51

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T18:59:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '994f1c89-8080-4c70-b5dd-9e1c92cca37f'	System	26 Aug 2020 22:59:51
User entered '97.9'	System	26 Aug 2020 22:59:51

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T18:59:41', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '994f1c89-8080-4c70-b5dd-9e1c92cca37f'	System	26 Aug 2020 22:59:51
User entered 'No (N)'	System	26 Aug 2020 22:59:51

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T18:59:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '994f1c89-8080-4c70-b5dd-9e1c92cca37f'	System	26 Aug 2020 22:59:51
User entered '26 Aug 2020 18:59'	System	26 Aug 2020 22:59:51

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '26 Aug 2020 15:50'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 2'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:12:52', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8'	System	27 Aug 2020 18:13:36
User entered 'Yes (Y)'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:13:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8'	System	27 Aug 2020 18:13:36
User entered '100.2'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:13:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8'	System	27 Aug 2020 18:13:36
User entered 'Yes (Y)'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User closed query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System). Query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' answered with 'spoke to subject' (Site from System).		03 Sep 2020 10:34:23
		02 Sep 2020 21:15:26
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	System	27 Aug 2020 18:13:36
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:13:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8'	System	27 Aug 2020 18:13:36
User entered '1'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:13:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8'	System	27 Aug 2020 18:13:36
User entered '0'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:13:30', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f10024dd-9be5-4c4c-9f00-1e96e64b61c8'	System	27 Aug 2020 18:13:36
User entered '27 Aug 2020 14:13'	System	27 Aug 2020 18:13:36

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 3'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:02:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '8b483141-94ed-465a-aa92-50d9466bb4f3'	System	28 Aug 2020 22:03:17
User entered 'Yes (Y)'	System	28 Aug 2020 22:03:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:06', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '8b483141-94ed-465a-aa92-50d9466bb4f3'	System	28 Aug 2020 22:03:17
User entered '98.8'	System	28 Aug 2020 22:03:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '8b483141-94ed-465a-aa92-50d9466bb4f3'	System	28 Aug 2020 22:03:17
User entered 'No (N)'	System	28 Aug 2020 22:03:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '8b483141-94ed-465a-aa92-50d9466bb4f3'	System	28 Aug 2020 22:03:17
User entered '28 Aug 2020 18:03'	System	28 Aug 2020 22:03:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 4'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:04:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3776e44c-c924-4878-8415-22659ee923b4'	System	29 Aug 2020 22:05:02
User entered 'Yes (Y)'	System	29 Aug 2020 22:05:02

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:04:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3776e44c-c924-4878-8415-22659ee923b4'	System	29 Aug 2020 22:05:02
User entered '97.7'	System	29 Aug 2020 22:05:02

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:04:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3776e44c-c924-4878-8415-22659ee923b4'	System	29 Aug 2020 22:05:02
User entered 'No (N)'	System	29 Aug 2020 22:05:02

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:04:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3776e44c-c924-4878-8415-22659ee923b4'	System	29 Aug 2020 22:05:02
User entered '29 Aug 2020 18:04'	System	29 Aug 2020 22:05:02

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 5'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:41:39', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd72324f5-d9d5-4242-a7f3-0a30d60dc971'	System	30 Aug 2020 23:42:01
User entered 'Yes (Y)'	System	30 Aug 2020 23:42:01

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:41:50', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd72324f5-d9d5-4242-a7f3-0a30d60dc971'	System	30 Aug 2020 23:42:01
User entered '97.6'	System	30 Aug 2020 23:42:01

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:41:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd72324f5-d9d5-4242-a7f3-0a30d60dc971'	System	30 Aug 2020 23:42:01
User entered 'No (N)'	System	30 Aug 2020 23:42:01

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:41:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'd72324f5-d9d5-4242-a7f3-0a30d60dc971'	System	30 Aug 2020 23:42:01
User entered '30 Aug 2020 19:41'	System	30 Aug 2020 23:42:01

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 6'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f2346526-8092-4460-b932-532ec2439888'	System	31 Aug 2020 19:31:17
User entered 'Yes (Y)'	System	31 Aug 2020 19:31:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:24', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f2346526-8092-4460-b932-532ec2439888'	System	31 Aug 2020 19:31:17
User entered '97.9'	System	31 Aug 2020 19:31:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:28', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f2346526-8092-4460-b932-532ec2439888'	System	31 Aug 2020 19:31:17
User entered 'No (N)'	System	31 Aug 2020 19:31:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'f2346526-8092-4460-b932-532ec2439888'	System	31 Aug 2020 19:31:17
User entered '31 Aug 2020 15:27'	System	31 Aug 2020 19:31:17

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 7'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '65b7bc5e-9c1c-4af6-9b77-51f722ace173'	System	01 Sep 2020 21:16:48
User entered 'Yes (Y)'	System	01 Sep 2020 21:16:48

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:36', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '65b7bc5e-9c1c-4af6-9b77-51f722ace173'	System	01 Sep 2020 21:16:48
User entered '98.2'	System	01 Sep 2020 21:16:48

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '65b7bc5e-9c1c-4af6-9b77-51f722ace173'	System	01 Sep 2020 21:16:48
User entered 'No (N)'	System	01 Sep 2020 21:16:48

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '65b7bc5e-9c1c-4af6-9b77-51f722ace173'	System	01 Sep 2020 21:16:48
User entered '01 Sep 2020 17:16'	System	01 Sep 2020 21:16:48

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '25fc8693-6c03-4877-9ecf-5875baef0cf2'	System	26 Aug 2020 16:37:47
User entered 'None (1)'	System	26 Aug 2020 16:37:47

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '25fc8693-6c03-4877-9ecf-5875baef0cf2'	System	26 Aug 2020 16:37:47
User entered 'No (N)'	System	26 Aug 2020 16:37:47

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '25fc8693-6c03-4877-9ecf-5875baef0cf2'	System	26 Aug 2020 16:37:47
User entered 'No (N)'	System	26 Aug 2020 16:37:47

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '25fc8693-6c03-4877-9ecf-5875baef0cf2'	System	26 Aug 2020 16:37:47
User entered 'None (1)'	System	26 Aug 2020 16:37:47

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '25fc8693-6c03-4877-9ecf-5875baef0cf2'	System	26 Aug 2020 16:37:47
User entered '26 Aug 2020 12:37'	System	26 Aug 2020 16:37:47

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '26 Aug 2020 12:25'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '26 Aug 2020 14:55'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:11', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2d327a8b-749b-416c-8501-ebf7f5ae4d2c'	System	26 Aug 2020 23:00:32
User entered 'Does not interfere with activity (2)'	System	26 Aug 2020 23:00:32

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2d327a8b-749b-416c-8501-ebf7f5ae4d2c'	System	26 Aug 2020 23:00:32
User entered 'No (N)'	System	26 Aug 2020 23:00:32

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2d327a8b-749b-416c-8501-ebf7f5ae4d2c'	System	26 Aug 2020 23:00:32
User entered 'No (N)'	System	26 Aug 2020 23:00:32

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2d327a8b-749b-416c-8501-ebf7f5ae4d2c'	System	26 Aug 2020 23:00:32
User entered 'None (1)'	System	26 Aug 2020 23:00:32

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2d327a8b-749b-416c-8501-ebf7f5ae4d2c'	System	26 Aug 2020 23:00:32
User entered '26 Aug 2020 19:00'	System	26 Aug 2020 23:00:32

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '26 Aug 2020 15:50'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 2'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:04', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e11da5d2-11e7-4557-be4c-bbf8fb1ae0e2'	System	27 Aug 2020 18:14:25
User entered 'Does not interfere with activity (2)'	System	27 Aug 2020 18:14:25

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e11da5d2-11e7-4557-be4c-bbf8fb1ae0e2'	System	27 Aug 2020 18:14:25
User entered 'No (N)'	System	27 Aug 2020 18:14:25

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:11', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e11da5d2-11e7-4557-be4c-bbf8fb1ae0e2'	System	27 Aug 2020 18:14:25
User entered 'No (N)'	System	27 Aug 2020 18:14:25

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e11da5d2-11e7-4557-be4c-bbf8fb1ae0e2'	System	27 Aug 2020 18:14:25
User entered 'None (1)'	System	27 Aug 2020 18:14:25

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:21', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e11da5d2-11e7-4557-be4c-bbf8fb1ae0e2'	System	27 Aug 2020 18:14:25
User entered '27 Aug 2020 14:14'	System	27 Aug 2020 18:14:25

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 3'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'dc927a67-adb9-4f8a-ae9a-3c10a1d12c2f'	System	28 Aug 2020 22:03:41
User entered 'Does not interfere with activity (2)'	System	28 Aug 2020 22:03:41

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:23', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'dc927a67-adb9-4f8a-ae9a-3c10a1d12c2f'	System	28 Aug 2020 22:03:41
User entered 'No (N)'	System	28 Aug 2020 22:03:41

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:25', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'dc927a67-adb9-4f8a-ae9a-3c10a1d12c2f'	System	28 Aug 2020 22:03:41
User entered 'No (N)'	System	28 Aug 2020 22:03:41

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:30', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'dc927a67-adb9-4f8a-ae9a-3c10a1d12c2f'	System	28 Aug 2020 22:03:41
User entered 'None (1)'	System	28 Aug 2020 22:03:41

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:36', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'dc927a67-adb9-4f8a-ae9a-3c10a1d12c2f'	System	28 Aug 2020 22:03:41
User entered '28 Aug 2020 18:03'	System	28 Aug 2020 22:03:41

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 4'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:04', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ab69582c-1269-4280-a39c-5793fc904313'	System	29 Aug 2020 22:05:20
User entered 'None (1)'	System	29 Aug 2020 22:05:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ab69582c-1269-4280-a39c-5793fc904313'	System	29 Aug 2020 22:05:20
User entered 'No (N)'	System	29 Aug 2020 22:05:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ab69582c-1269-4280-a39c-5793fc904313'	System	29 Aug 2020 22:05:20
User entered 'No (N)'	System	29 Aug 2020 22:05:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:13', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ab69582c-1269-4280-a39c-5793fc904313'	System	29 Aug 2020 22:05:20
User entered 'None (1)'	System	29 Aug 2020 22:05:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ab69582c-1269-4280-a39c-5793fc904313'	System	29 Aug 2020 22:05:20
User entered '29 Aug 2020 18:05'	System	29 Aug 2020 22:05:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 5'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:01', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '77a84680-b8c9-40bc-84d3-19462634bc8b'	System	30 Aug 2020 23:42:20
User entered 'None (1)'	System	30 Aug 2020 23:42:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:06', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '77a84680-b8c9-40bc-84d3-19462634bc8b'	System	30 Aug 2020 23:42:20
User entered 'No (N)'	System	30 Aug 2020 23:42:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '77a84680-b8c9-40bc-84d3-19462634bc8b'	System	30 Aug 2020 23:42:20
User entered 'No (N)'	System	30 Aug 2020 23:42:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:12', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '77a84680-b8c9-40bc-84d3-19462634bc8b'	System	30 Aug 2020 23:42:20
User entered 'None (1)'	System	30 Aug 2020 23:42:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:15', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '77a84680-b8c9-40bc-84d3-19462634bc8b'	System	30 Aug 2020 23:42:20
User entered '30 Aug 2020 19:42'	System	30 Aug 2020 23:42:20

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 6'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fff44811-320f-4df0-b7c7-2c7950e7a175'	System	31 Aug 2020 19:31:23
User entered 'None (1)'	System	31 Aug 2020 19:31:23

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fff44811-320f-4df0-b7c7-2c7950e7a175'	System	31 Aug 2020 19:31:23
User entered 'No (N)'	System	31 Aug 2020 19:31:23

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:45', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fff44811-320f-4df0-b7c7-2c7950e7a175'	System	31 Aug 2020 19:31:23
User entered 'No (N)'	System	31 Aug 2020 19:31:23

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fff44811-320f-4df0-b7c7-2c7950e7a175'	System	31 Aug 2020 19:31:23
User entered 'None (1)'	System	31 Aug 2020 19:31:23

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:52', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'fff44811-320f-4df0-b7c7-2c7950e7a175'	System	31 Aug 2020 19:31:23
User entered '31 Aug 2020 15:27'	System	31 Aug 2020 19:31:23

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 7'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5ec26aac-3b83-4e2d-985e-73073286fdfa'	System	01 Sep 2020 21:17:10
User entered 'None (1)'	System	01 Sep 2020 21:17:10

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5ec26aac-3b83-4e2d-985e-73073286fdfa'	System	01 Sep 2020 21:17:10
User entered 'No (N)'	System	01 Sep 2020 21:17:10

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:16:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5ec26aac-3b83-4e2d-985e-73073286fdfa'	System	01 Sep 2020 21:17:10
User entered 'No (N)'	System	01 Sep 2020 21:17:10

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5ec26aac-3b83-4e2d-985e-73073286fdfa'	System	01 Sep 2020 21:17:10
User entered 'None (1)'	System	01 Sep 2020 21:17:10

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:04', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5ec26aac-3b83-4e2d-985e-73073286fdfa'	System	01 Sep 2020 21:17:10
User entered '01 Sep 2020 17:17'	System	01 Sep 2020 21:17:10

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:50', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:37:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:38:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:38:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:38:11', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'None (0)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:38:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered 'No (N)'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T12:38:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2c6d26bc-99be-4391-8b10-d034bc264dd0'	System	26 Aug 2020 16:38:27
User entered '26 Aug 2020 12:38'	System	26 Aug 2020 16:38:27

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '26 Aug 2020 12:25'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '26 Aug 2020 14:55'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 1, after vaccination (at home)'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:36', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:00:59', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'None (0)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:01:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered 'No (N)'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-26T19:01:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'cb50494f-d160-4254-94df-e8416874851d'	System	26 Aug 2020 23:01:21
User entered '26 Aug 2020 19:01'	System	26 Aug 2020 23:01:21

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '26 Aug 2020 15:50'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '27 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 2'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:32', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'No interference with activity (1)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'Some interference with activity (2)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:45', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'Some interference with activity (2)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:14:52', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'Some interference with activity (2)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:15:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'None (0)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:15:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'No interference with activity (1)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:15:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered 'No (N)'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-27T14:15:37', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '9c85b5b8-6acb-42ad-b6a4-4837aa39e262'	System	27 Aug 2020 18:15:42
User entered '27 Aug 2020 14:15'	System	27 Aug 2020 18:15:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '27 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '28 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 3'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcba4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcba4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcba4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcba4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcba4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:03:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcba4f'	System	28 Aug 2020 22:04:11
User entered 'None (0)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:04:02', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcba4f'	System	28 Aug 2020 22:04:11
User entered 'No (N)'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-28T18:04:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '84a3cc5a-2235-4c13-a801-125d1fcba4f'	System	28 Aug 2020 22:04:11
User entered '28 Aug 2020 18:04'	System	28 Aug 2020 22:04:11

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '28 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 4'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:25', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:31', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:36', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'None (0)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:41', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered 'No (N)'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-29T18:05:45', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bf3fcab3-3c5b-4616-b93f-a169afa0af88'	System	29 Aug 2020 22:05:49
User entered '29 Aug 2020 18:05'	System	29 Aug 2020 22:05:49

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '29 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 5'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:20', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:25', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:29', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:31', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'None (0)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered 'No (N)'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-30T19:42:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '4f681d5b-e135-489c-8955-737dbba3e6d4'	System	30 Aug 2020 23:42:43
User entered '30 Aug 2020 19:42'	System	30 Aug 2020 23:42:43

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '30 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Aug 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 6'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:27:57', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:02', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:08', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:13', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'None (0)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:16', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered 'No (N)'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-08-31T15:28:25', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2f048b64-24fb-43da-8900-52e32af3ad16'	System	31 Aug 2020 19:31:31
User entered '31 Aug 2020 15:28'	System	31 Aug 2020 19:31:31

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '31 Aug 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	26 Aug 2020 16:09:42
User entered 'Day 7'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:12', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:14', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:19', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:22', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'None (0)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:24', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered 'No (N)'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-09-01T17:17:28', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'e4880247-6ec8-41d9-aa0a-8854c2219c83'	System	01 Sep 2020 21:17:32
User entered '01 Sep 2020 17:17'	System	01 Sep 2020 21:17:32

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '01 Sep 2020 12:00'	System	26 Aug 2020 16:09:42

US3412013

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:24:56

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
User entered '02 Sep 2020 11:59'	System	26 Aug 2020 16:09:42

US3412013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:42:34
User entered 'Yes (Y)'		02 Sep 2020 21:14:45

US3412013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:42:34
User entered '02 Sep 2020'		02 Sep 2020 21:14:45

US3412013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:42:34
User entered 'Contact Made (CONTACT MADE)'		02 Sep 2020 21:14:45

US3412013

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:42:34
User entered empty.		02 Sep 2020 21:14:45

US3412013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:21:13
DataPoint Verified.	(b) (4), (b) (6)	09 Sep 2020 15:42:45
User entered 'Yes (Y)'		02 Sep 2020 21:14:51

US3412013

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'I'	System	02 Sep 2020 21:14:51

US3412013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:39:39
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	09 Sep 2020 19:49:42

US3412013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:39:39
User entered '9 Sep 2020'	Mason Urban (b) (4) (b) (4)	09 Sep 2020 19:49:42

US3412013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:39:39
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	09 Sep 2020 19:49:42

US3412013

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:39:39
User entered empty.	Mason Urban (b) (4) (b) (4)	09 Sep 2020 19:49:42

US3412013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:39:44
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	09 Sep 2020 19:50:01

US3412013

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'I'	System	09 Sep 2020 19:50:01

US3412013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:40:01
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	16 Sep 2020 20:15:47

US3412013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:40:01
User entered '16 Sep 2020'	Mason Urban (b) (4) (b) (4)	16 Sep 2020 20:15:47

US3412013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:40:01
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	16 Sep 2020 20:15:47

US3412013

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:40:01
User entered empty.	Mason Urban (b) (4) (b) (4)	16 Sep 2020 20:15:47

US3412013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:43
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:40:04
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	16 Sep 2020 20:15:38

US3412013

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'I'	System	16 Sep 2020 20:15:38

US3412013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:44
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:10:42

US3412013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

Visit date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:44
User entered '24 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:10:42

US3412013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[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 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:44
User entered 'Clinic (Clinic)'	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:10:42

US3412013

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'VISIT3'	System	29 Sep 2020 16:10:42

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered 'No (N)'	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered empty.	System	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered empty.	System	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered empty.	System	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered empty.	System	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:42:51
User entered empty.	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered empty.	System	29 Sep 2020 16:11:16

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30

US3412013

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30

US3412013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

Was the physical examination performed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:43
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 17:07:29
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 17:07:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:43:17
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:33

US3412013

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:48:43
DataPoint Un-verified.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 17:07:29
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 17:07:29
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:43:17
User entered '24 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:11:33

US3412013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
User closed query 'Per IMMUNO Lab Recon: it appears a sample was collected on 24Sep2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail' (Site from DM).	(b) (4) (b) (4), (b) (6)	30 Nov 2020 08:52:47
Query 'Per IMMUNO Lab Recon: it appears a sample was collected on 24Sep2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail' answered with 'Samples were shipped with AWB:910890148110 on 24SEP2020. We have a received a specimen received report indicating Immuno11-24 was received. ' (Site from DM).	Mylene Asmar-Rios (b) (4)	12 Oct 2020 13:26:58
User opened query 'Per IMMUNO Lab Recon: it appears a sample was collected on 24Sep2020; however, it has not been received by GCL. Please clarify and, if shipped, please provide tracking detail' (Site from DM).	(b) (4), (b) (6)	07 Oct 2020 01:03:03
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 15:43:27
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:12:05

US3412013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:43:27
User entered '24 Sep 2020'	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:12:05

US3412013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:43:27
User entered '12:09'	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:12:05

US3412013

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered '24 Sep 2020 12:09'	System	29 Sep 2020 16:12:05

US3412013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 00:40:45
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 15:43:55
User entered 'Yes (Y)'	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:12:13

US3412013

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'I'	System	29 Sep 2020 16:12:13

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 64'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:51:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered 'Yes (Y)'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Have you been exposed to someone with 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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:51:57', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered 'No (N)'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:08', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered 'Yes (Y)'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '1'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '0'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:52:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:53:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered 'No (N)'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-01T15:53:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'bca5cfca-8e16-423b-8e3b-2c93af97ca2b'	System	01 Oct 2020 19:53:19
User entered '01 Oct 2020 15:53:07'	System	01 Oct 2020 19:53:19

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '28 Sep 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '02 Oct 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 71'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-07T18:04:21', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '955ead50-8394-4be1-ac54-9ea2521e49cb'	System	07 Oct 2020 22:04:36
User entered 'No (N)'	System	07 Oct 2020 22:04:36

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Have you been exposed to someone with 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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-07T18:04:24', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '955ead50-8394-4be1-ac54-9ea2521e49cb'	System	07 Oct 2020 22:04:36
User entered 'No (N)'	System	07 Oct 2020 22:04:36

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-07T18:04:30', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '955ead50-8394-4be1-ac54-9ea2521e49cb'	System	07 Oct 2020 22:04:36
User entered '07 Oct 2020 18:04:30'	System	07 Oct 2020 22:04:36

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '05 Oct 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '09 Oct 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 78'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-12T00:02:05', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6482ce6a-8574-4a74-ab2b-2fff392a8509'	System	12 Oct 2020 04:02:17
User entered 'No (N)'	System	12 Oct 2020 04:02:17

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Have you been exposed to someone with 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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-12T00:02:09', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6482ce6a-8574-4a74-ab2b-2fff392a8509'	System	12 Oct 2020 04:02:17
User entered 'No (N)'	System	12 Oct 2020 04:02:17

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-12T00:02:15', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6482ce6a-8574-4a74-ab2b-2fff392a8509'	System	12 Oct 2020 04:02:17
User entered '12 Oct 2020 00:02:15'	System	12 Oct 2020 04:02:17

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '12 Oct 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '16 Oct 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 92'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-26T12:25:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '33deb048-fb42-4792-9527-e52a316c63c3'	System	26 Oct 2020 16:26:00
User entered 'No (N)'	System	26 Oct 2020 16:26:00

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-26T12:25:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '33deb048-fb42-4792-9527-e52a316c63c3'	System	26 Oct 2020 16:26:00
User entered 'No (N)'	System	26 Oct 2020 16:26:00

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-10-26T12:25:54', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '33deb048-fb42-4792-9527-e52a316c63c3'	System	26 Oct 2020 16:26:00
User entered '26 Oct 2020 12:25:54'	System	26 Oct 2020 16:26:00

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '26 Oct 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '30 Oct 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 99'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-02T06:20:45', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5f79f44b-2be1-4c1a-8ce8-b1f97a605c7b'	System	02 Nov 2020 11:21:05
User entered 'No (N)'	System	02 Nov 2020 11:21:05

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Have you been exposed to someone with 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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-02T06:20:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5f79f44b-2be1-4c1a-8ce8-b1f97a605c7b'	System	02 Nov 2020 11:21:05
User entered 'No (N)'	System	02 Nov 2020 11:21:05

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-02T06:20:59', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5f79f44b-2be1-4c1a-8ce8-b1f97a605c7b'	System	02 Nov 2020 11:21:05
User entered '02 Nov 2020 06:20:59'	System	02 Nov 2020 11:21:05

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '02 Nov 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '06 Nov 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 106'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-09T17:55:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6cd99fbd-9168-421f-a09d-2e9084bf88d7'	System	09 Nov 2020 22:55:53
User entered 'No (N)'	System	09 Nov 2020 22:55:53

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Have you been exposed to someone with 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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-09T17:55:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6cd99fbd-9168-421f-a09d-2e9084bf88d7'	System	09 Nov 2020 22:55:53
User entered 'No (N)'	System	09 Nov 2020 22:55:53

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-09T17:55:48', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6cd99fbd-9168-421f-a09d-2e9084bf88d7'	System	09 Nov 2020 22:55:53
User entered '09 Nov 2020 17:55:48'	System	09 Nov 2020 22:55:53

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '09 Nov 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '13 Nov 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered 'Day 113'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-16T18:28:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ffdd3ef4-c979-4e1e-a289-3a96aaa8b7ff'	System	16 Nov 2020 23:28:48
User entered 'No (N)'	System	16 Nov 2020 23:28:48

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Have you been exposed to someone with 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 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-16T18:28:40', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ffdd3ef4-c979-4e1e-a289-3a96aaa8b7ff'	System	16 Nov 2020 23:28:48
User entered 'No (N)'	System	16 Nov 2020 23:28:48

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-16T18:28:44', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'ffdd3ef4-c979-4e1e-a289-3a96aaa8b7ff'	System	16 Nov 2020 23:28:48
User entered '16 Nov 2020 18:28:44'	System	16 Nov 2020 23:28:48

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '16 Nov 2020 00:01'	System	29 Jul 2020 17:03:20

US3412013

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 09:25:49
Data entry locked.	System	29 Jul 2020 17:03:20
User entered '20 Nov 2020 23:59'	System	29 Jul 2020 17:03:20

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2020-11-22T14:16:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered 'Yes (Y)'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2020-11-22T14:16:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered 'No (N)'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-22T14:16:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered 'No (N)'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-22T14:17:04', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered 'Yes (Y)'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-22T14:17:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-22T14:17:15', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '333305dc-fb08-4984-b771-ee3f3195b59d'	System	22 Nov 2020 19:17:28
User entered '22 Nov 2020 14:17:15'	System	22 Nov 2020 19:17:28

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 Nov 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 Nov 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2020-11-27T13:54:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '17265cb3-c43c-4f23-9195-c5b96864a3dd'	System	27 Nov 2020 18:55:03
User entered 'No (N)'	System	27 Nov 2020 18:55:03

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2020-11-27T13:54:53', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '17265cb3-c43c-4f23-9195-c5b96864a3dd'	System	27 Nov 2020 18:55:03
User entered 'No (N)'	System	27 Nov 2020 18:55:03

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-11-27T13:54:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '17265cb3-c43c-4f23-9195-c5b96864a3dd' User entered '27 Nov 2020 13:54:58'	System	27 Nov 2020 18:55:03
	System	27 Nov 2020 18:55:03

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 Nov 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Dec 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2020-12-07T20:56:31', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6625794a-0f18-4d25-bd5f-8eb81a6be7ed'	System	08 Dec 2020 01:56:48
User entered 'No (N)'	System	08 Dec 2020 01:56:48

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2020-12-07T20:56:37', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6625794a-0f18-4d25-bd5f-8eb81a6be7ed'	System	08 Dec 2020 01:56:48
User entered 'No (N)'	System	08 Dec 2020 01:56:48

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-12-07T20:56:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '6625794a-0f18-4d25-bd5f-8eb81a6be7ed'	System	08 Dec 2020 01:56:48
User entered '07 Dec 2020 20:56:42'	System	08 Dec 2020 01:56:48

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Dec 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Dec 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2020-12-11T23:31:58', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '39716aec-4828-4e1d-a168-1534d67819fd'	System	12 Dec 2020 04:32:19
User entered 'No (N)'	System	12 Dec 2020 04:32:19

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2020-12-11T23:32:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '39716aec-4828-4e1d-a168-1534d67819fd'	System	12 Dec 2020 04:32:19
User entered 'No (N)'	System	12 Dec 2020 04:32:19

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-12-11T23:32:12', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '39716aec-4828-4e1d-a168-1534d67819fd' User entered '11 Dec 2020 23:32:12'	System	12 Dec 2020 04:32:19
	System	12 Dec 2020 04:32:19

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 Dec 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Dec 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2020-12-18T18:40:27', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'c09cd9ff-ebb0-42ad-94c9-cd691a1ac97a'	System	18 Dec 2020 23:40:44
User entered 'No (N)'	System	18 Dec 2020 23:40:44

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2020-12-18T18:40:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'c09cd9ff-ebb0-42ad-94c9-cd691a1ac97a'	System	18 Dec 2020 23:40:44
User entered 'No (N)'	System	18 Dec 2020 23:40:44

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-12-18T18:40:37', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'c09cd9ff-ebb0-42ad-94c9-cd691a1ac97a'	System	18 Dec 2020 23:40:44
User entered '18 Dec 2020 18:40:37'	System	18 Dec 2020 23:40:44

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 Dec 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Dec 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2020-12-28T14:40:10', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3bf83dbf-eccb-4232-b465-b44405fad7be'	System	28 Dec 2020 19:40:26
User entered 'No (N)'	System	28 Dec 2020 19:40:26

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2020-12-28T14:40:13', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3bf83dbf-eccb-4232-b465-b44405fad7be'	System	28 Dec 2020 19:40:26
User entered 'No (N)'	System	28 Dec 2020 19:40:26

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2020-12-28T14:40:18', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3bf83dbf-eccb-4232-b465-b44405fad7be'	System	28 Dec 2020 19:40:26
User entered '28 Dec 2020 14:40:18'	System	28 Dec 2020 19:40:26

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 Dec 2020 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Dec 2020 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-01-02T11:14:35', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5aefb9bf-e6ec-4f65-8635-cf1ef64f64cc'	System	02 Jan 2021 16:15:12
User entered 'No (N)'	System	02 Jan 2021 16:15:12

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-01-02T11:14:39', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5aefb9bf-e6ec-4f65-8635-cf1ef64f64cc'	System	02 Jan 2021 16:15:12
User entered 'Yes (Y)'	System	02 Jan 2021 16:15:12

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-01-02T11:14:49', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5aefb9bf-e6ec-4f65-8635-cf1ef64f64cc'	System	02 Jan 2021 16:15:12
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	02 Jan 2021 16:15:12

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-01-02T11:14:59', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5aefb9bf-e6ec-4f65-8635-cf1ef64f64cc'	System	02 Jan 2021 16:15:12
User entered '02 Jan 2021 11:14:59'	System	02 Jan 2021 16:15:12

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Jan 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Jan 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-01-10T18:15:33', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '22bc35cb-fd5d-4132-96bf-a91ceb174ad6'	System	10 Jan 2021 23:15:46
User entered 'No (N)'	System	10 Jan 2021 23:15:46

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-01-10T18:15:38', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '22bc35cb-fd5d-4132-96bf-a91ceb174ad6'	System	10 Jan 2021 23:15:46
User entered 'No (N)'	System	10 Jan 2021 23:15:46

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-01-10T18:15:41', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '22bc35cb-fd5d-4132-96bf-a91ceb174ad6' User entered '10 Jan 2021 18:15:41'	System	10 Jan 2021 23:15:46
	System	10 Jan 2021 23:15:46

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Jan 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Jan 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-01-15T00:03:07', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '173b7618-6885-4e07-8985-75da885bb80e'	System	15 Jan 2021 05:03:21
User entered 'No (N)'	System	15 Jan 2021 05:03:21

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-01-15T00:03:11', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '173b7618-6885-4e07-8985-75da885bb80e'	System	15 Jan 2021 05:03:21
User entered 'No (N)'	System	15 Jan 2021 05:03:21

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-01-15T00:03:16', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '173b7618-6885-4e07-8985-75da885bb80e'	System	15 Jan 2021 05:03:21
User entered '15 Jan 2021 00:03:16'	System	15 Jan 2021 05:03:21

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Jan 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Jan 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-01-22T00:01:41', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0e4606e5-2407-4f58-b50b-e776333f65d3'	System	22 Jan 2021 05:02:09
User entered 'No (N)'	System	22 Jan 2021 05:02:09

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-01-22T00:01:46', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0e4606e5-2407-4f58-b50b-e776333f65d3'	System	22 Jan 2021 05:02:09
User entered 'No (N)'	System	22 Jan 2021 05:02:09

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-01-22T00:01:51', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0e4606e5-2407-4f58-b50b-e776333f65d3'	System	22 Jan 2021 05:02:09
User entered '22 Jan 2021 00:01:51'	System	22 Jan 2021 05:02:09

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Jan 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Jan 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-02-02T12:20:26', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'de19f1a6-d8ed-4383-92c2-1f8cacfca1d4'	System	02 Feb 2021 17:20:44
User entered 'No (N)'	System	02 Feb 2021 17:20:44

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-02-02T12:20:30', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'de19f1a6-d8ed-4383-92c2-1f8cacfa1d4'	System	02 Feb 2021 17:20:44
User entered 'No (N)'	System	02 Feb 2021 17:20:44

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-02-02T12:20:34', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'de19f1a6-d8ed-4383-92c2-1f8cacfca1d4'	System	02 Feb 2021 17:20:44
User entered '02 Feb 2021 12:20:34'	System	02 Feb 2021 17:20:44

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Jan 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Feb 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-02-05T00:02:42', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '740a18ba-e233-4515-8ccf-cf152392b3e7'	System	05 Feb 2021 05:03:15
User entered 'No (N)'	System	05 Feb 2021 05:03:15

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-02-05T00:02:50', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '740a18ba-e233-4515-8ccf-cf152392b3e7'	System	05 Feb 2021 05:03:15
User entered 'No (N)'	System	05 Feb 2021 05:03:15

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-02-05T00:02:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '740a18ba-e233-4515-8ccf-cf152392b3e7'	System	05 Feb 2021 05:03:15
User entered '05 Feb 2021 00:02:56'	System	05 Feb 2021 05:03:15

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Feb 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Feb 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-02-12T05:23:06', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'a2942d06-1950-40a0-bd97-e3e70f2593dd'	System	12 Feb 2021 10:23:23
User entered 'No (N)'	System	12 Feb 2021 10:23:23

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-02-12T05:23:11', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'a2942d06-1950-40a0-bd97-e3e70f2593dd'	System	12 Feb 2021 10:23:23
User entered 'No (N)'	System	12 Feb 2021 10:23:23

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-02-12T05:23:17', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: 'a2942d06-1950-40a0-bd97-e3e70f2593dd' User entered '12 Feb 2021 05:23:17'	System	12 Feb 2021 10:23:23
	System	12 Feb 2021 10:23:23

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Feb 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Feb 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-02-19T16:54:52', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '600bc7f4-9b9e-4e05-89c7-bd8e7ac77e4d'	System	19 Feb 2021 22:12:01
User entered 'No (N)'	System	19 Feb 2021 22:12:01

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-02-19T16:54:56', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '600bc7f4-9b9e-4e05-89c7-bd8e7ac77e4d'	System	19 Feb 2021 22:12:01
User entered 'No (N)'	System	19 Feb 2021 22:12:01

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-02-19T16:55:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '600bc7f4-9b9e-4e05-89c7-bd8e7ac77e4d'	System	19 Feb 2021 22:12:01
User entered '19 Feb 2021 16:55:00'	System	19 Feb 2021 22:12:01

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Feb 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Feb 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-02-28T18:12:57-05:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5400e666-1326-4636-ae74-ff831a517e07' User entered 'No (N)'	System	28 Feb 2021 23:16:10
	System	28 Feb 2021 23:16:10

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-02-28T18:13:00-05:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5400e666-1326-4636-ae74-ff831a517e07' User entered 'No (N)'	System	28 Feb 2021 23:16:10
	System	28 Feb 2021 23:16:10

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-02-28T18:13:03-05:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '5400e666-1326-4636-ae74-ff831a517e07' User entered '28 Feb 2021 18:13:03'	System	28 Feb 2021 23:16:10
	System	28 Feb 2021 23:16:10

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Feb 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Mar 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-03-09T10:53:17-05:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '258f761e-5234-47cc-a7cb-15c69ac33fb7'	System	09 Mar 2021 15:53:32
User entered 'No (N)'	System	09 Mar 2021 15:53:32

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-03-09T10:53:21-05:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '258f761e-5234-47cc-a7cb-15c69ac33fb7'	System	09 Mar 2021 15:53:32
User entered 'No (N)'	System	09 Mar 2021 15:53:32

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-03-09T10:53:25-05:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '258f761e-5234-47cc-a7cb-15c69ac33fb7'	System	09 Mar 2021 15:53:32
User entered '09 Mar 2021 10:53:25'	System	09 Mar 2021 15:53:32

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Mar 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Mar 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-03-12T00:01:48-05:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0423a10e-546a-4fad-bbe5-ba4971e08a79'	System	12 Mar 2021 05:02:46
User entered 'No (N)'	System	12 Mar 2021 05:02:46

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-03-12T00:01:52-05:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0423a10e-546a-4fad-bbe5-ba4971e08a79'	System	12 Mar 2021 05:02:46
User entered 'No (N)'	System	12 Mar 2021 05:02:46

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-03-12T00:01:56-05:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '0423a10e-546a-4fad-bbe5-ba4971e08a79'	System	12 Mar 2021 05:02:46
User entered '12 Mar 2021 00:01:56'	System	12 Mar 2021 05:02:46

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Mar 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Mar 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-03-19T04:53:35-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '19a776e6-e2aa-4498-8ab6-877a420a98a4'	System	19 Mar 2021 08:53:53
User entered 'No (N)'	System	19 Mar 2021 08:53:53

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-03-19T04:53:40-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '19a776e6-e2aa-4498-8ab6-877a420a98a4'	System	19 Mar 2021 08:53:53
User entered 'No (N)'	System	19 Mar 2021 08:53:53

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-03-19T04:53:46-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '19a776e6-e2aa-4498-8ab6-877a420a98a4' User entered '19 Mar 2021 04:53:46'	System	19 Mar 2021 08:53:53
	System	19 Mar 2021 08:53:53

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Mar 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Mar 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-03-28T12:46:40-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '736deddf-0e36-4d5d-87b1-5b616cfbf7f5'	System	28 Mar 2021 16:46:59
User entered 'No (N)'	System	28 Mar 2021 16:46:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-03-28T12:46:46-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '736deddf-0e36-4d5d-87b1-5b616cfbf7f5'	System	28 Mar 2021 16:46:59
User entered 'No (N)'	System	28 Mar 2021 16:46:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-03-28T12:46:51-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '736deddf-0e36-4d5d-87b1-5b616cfbf7f5'	System	28 Mar 2021 16:46:59
User entered '28 Mar 2021 12:46:51'	System	28 Mar 2021 16:46:59

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Mar 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Mar 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Apr 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 Apr 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Apr 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 Apr 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-04-20T20:35:28-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3de442e4-bb0b-420b-a732-75865e2576e4'	System	21 Apr 2021 00:35:41
User entered 'No (N)'	System	21 Apr 2021 00:35:41

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-04-20T20:35:33-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3de442e4-bb0b-420b-a732-75865e2576e4'	System	21 Apr 2021 00:35:41
User entered 'No (N)'	System	21 Apr 2021 00:35:41

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-04-20T20:35:36-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '3de442e4-bb0b-420b-a732-75865e2576e4'	System	21 Apr 2021 00:35:41
User entered '20 Apr 2021 20:35:36'	System	21 Apr 2021 00:35:41

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Apr 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 Apr 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-04-23T18:43:32-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2280094a-7e37-4c71-9ab4-58842eb31312'	System	23 Apr 2021 22:43:45
User entered 'No (N)'	System	23 Apr 2021 22:43:45

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-04-23T18:43:36-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2280094a-7e37-4c71-9ab4-58842eb31312'	System	23 Apr 2021 22:43:45
User entered 'No (N)'	System	23 Apr 2021 22:43:45

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-04-23T18:43:40-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '2280094a-7e37-4c71-9ab4-58842eb31312'	System	23 Apr 2021 22:43:45
User entered '23 Apr 2021 18:43:40'	System	23 Apr 2021 22:43:45

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Apr 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 Apr 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[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 (c44ed63bfc4063fb)', Time: '2021-05-03T11:01:19-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '78e6a4ad-d3ed-45c3-bfbe-86dbdc7831c0'	System	03 May 2021 15:01:50
User entered 'No (N)'	System	03 May 2021 15:01:50

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

Have you been exposed to someone with 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 (c44ed63bfc4063fb)', Time: '2021-05-03T11:01:23-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '78e6a4ad-d3ed-45c3-bfbe-86dbdc7831c0'	System	03 May 2021 15:01:50
User entered 'No (N)'	System	03 May 2021 15:01:50

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Date and time of submission](#)

Audit	User	Time (GMT)
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-05-03T11:01:26-04:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '78e6a4ad-d3ed-45c3-bfbe-86dbdc7831c0'	System	03 May 2021 15:01:50
User entered '03 May 2021 11:01:26'	System	03 May 2021 15:01:50

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Apr 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 May 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '07 May 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 May 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '14 May 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 May 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '21 May 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 May 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '28 May 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Jun 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Jun 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Jun 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 Jun 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Jun 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 Jun 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Jun 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 Jun 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Jun 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Jul 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 Jul 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Jul 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 Jul 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Jul 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 Jul 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Jul 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 Jul 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Jul 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '03 Aug 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 Aug 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '10 Aug 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 Aug 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '17 Aug 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 Aug 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 Aug 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 Aug 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '31 Aug 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '03 Sep 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '07 Sep 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '10 Sep 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '14 Sep 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '17 Sep 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '21 Sep 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 Sep 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '28 Sep 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Oct 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Oct 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Oct 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Oct 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Oct 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Oct 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Oct 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Oct 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Oct 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Nov 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Nov 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Nov 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Nov 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Nov 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Nov 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Nov 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Nov 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Nov 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '03 Dec 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '07 Dec 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '10 Dec 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '14 Dec 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '17 Dec 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '21 Dec 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 Dec 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '28 Dec 2021 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '31 Dec 2021 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Jan 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '07 Jan 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 Jan 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '14 Jan 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 Jan 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '21 Jan 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 Jan 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '28 Jan 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Feb 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Feb 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Feb 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 Feb 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Feb 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 Feb 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Feb 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 Feb 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Mar 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Mar 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Mar 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '11 Mar 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Mar 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '18 Mar 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Mar 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '25 Mar 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Mar 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Apr 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Apr 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Apr 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Apr 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Apr 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Apr 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Apr 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Apr 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Apr 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '03 May 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 May 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '10 May 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 May 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '17 May 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 May 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 May 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 May 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '31 May 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '03 Jun 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '07 Jun 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '10 Jun 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '14 Jun 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '17 Jun 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '21 Jun 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '24 Jun 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '28 Jun 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '01 Jul 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Jul 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '08 Jul 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Jul 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '15 Jul 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Jul 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '22 Jul 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Jul 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '29 Jul 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Aug 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '05 Aug 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Aug 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '12 Aug 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Aug 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '19 Aug 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Aug 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '26 Aug 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Aug 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '02 Sep 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '06 Sep 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '09 Sep 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '13 Sep 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '16 Sep 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '20 Sep 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '23 Sep 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '27 Sep 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '30 Sep 2022 00:01'	System	19 Nov 2020 02:46:38

US3412013

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:24:56

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 02:46:38
Amendment Manager: User entered '04 Oct 2022 23:59'	System	19 Nov 2020 02:46:38

US3412013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:24:56

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 23:28:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-03-12T00:02:11-05:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '42da6ff0-4f08-4b46-b1ef-aca587c68df3'	System	12 Mar 2021 05:03:22
User entered 'No (N)'	System	12 Mar 2021 05:03:22

US3412013

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary (1)

Generated On: 09 Jun 2021 17:24:56

[Date & Time of Submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Apr 2021 23:28:27
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (c44ed63bfc4063fb)', Time: '2021-03-12T00:02:23-05:00', User OID: 'PatientReportedOutcome (US3412013)', ODM File OID: '42da6ff0-4f08-4b46-b1ef-aca587c68df3'	System	12 Mar 2021 05:03:22
User entered '12 Mar 2021 00:02:23'	System	12 Mar 2021 05:03:22

US3412013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:11:21
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	22 Oct 2020 16:33:39

US3412013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:11:21
User entered '22 Oct 2020'	Mason Urban (b) (4) (b) (4)	22 Oct 2020 16:33:39

US3412013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:11:21
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	22 Oct 2020 16:33:39

US3412013

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:11:21
User entered empty.	Mason Urban (b) (4) (b) (4)	22 Oct 2020 16:33:39

US3412013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User signature succeeded.	Richard Powell (b) (4)	10 Mar 2021 19:25:52
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:11:24
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	22 Oct 2020 16:33:46

US3412013

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	27 Mar 2021 19:12:30
User entered 'I'	System	22 Oct 2020 16:33:46

US3412013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:22:41
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	07 Dec 2020 18:43:31

US3412013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:22:41
User entered '25 Nov 2020'	Steven Anderson (b) (4) (b) (4)	07 Dec 2020 18:43:31

US3412013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:22:41
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4) (b) (4)	07 Dec 2020 18:43:31

US3412013

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:22:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	07 Dec 2020 18:43:31

US3412013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:23:01
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	07 Dec 2020 18:43:42

US3412013

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User entered 'I'	System	07 Dec 2020 18:43:42

US3412013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:14:46
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	23 Dec 2020 17:00:52

US3412013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:14:46
User entered '23 Dec 2020'	Mason Urban (b) (4)	23 Dec 2020 17:00:52

US3412013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:14:46
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	23 Dec 2020 17:00:52

US3412013

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:14:46
User entered empty.	Mason Urban (b) (4)	23 Dec 2020 17:00:52

US3412013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:14:50
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	23 Dec 2020 17:00:41

US3412013

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User entered 'I'	System	23 Dec 2020 17:00:41

US3412013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:48:03
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	25 Jan 2021 20:32:13

US3412013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:48:03
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Please confirm date of sample. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 11:28:58
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).		22 Feb 2021 11:28:56
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Please confirm date of sample. Else clarify, thank you.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	17 Feb 2021 13:20:00
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	17 Feb 2021 13:19:56

US3412013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 18Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Please confirm date of sample. Else clarify, thank you.' (Site from DM).	(b) (4), (b) (6)	08 Feb 2021 16:03:00
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' canceled (Site from DM).		08 Feb 2021 16:02:32
User opened query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 25Jan2021 is reported under OL-1 visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you.' (Site from DM).		08 Feb 2021 16:02:22
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 18-JAN-2021 is reported under OL-1 visit in PPD portal; however, the same is missing in EDC. Kindly review if the sample was collected, if yes, update the data as appropriate under Central Laboratory - Nasopharyngeal Swab (Single) eCRF initiated under Participant Decision Visit / OL-D1 eCRF, else clarify. ' (Site from DM).		08 Feb 2021 09:40:10
User entered '25 Jan 2021'	Mason Urban (b) (4) (b) (4)	25 Jan 2021 20:32:13

US3412013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:48:03
User entered 'Contact Made (CONTACT MADE)'	Mason Urban (b) (4) (b) (4)	25 Jan 2021 20:32:13

US3412013

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:48:03
User entered empty.	Mason Urban (b) (4)	25 Jan 2021 20:32:13

US3412013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:48:07
User entered 'Yes (Y)'	Mason Urban (b) (4) (b) (4)	25 Jan 2021 20:32:00

US3412013

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User entered 'I'	System	25 Jan 2021 20:32:00

US3412013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:55:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:08:29

US3412013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:55:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:08:29

US3412013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[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 04:46:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:55:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered 'Clinic (Clinic)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:08:29

US3412013

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User entered 'VISIT4'	System	25 Mar 2021 13:08:29

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:55:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 19:13:17

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Date of assessment (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:55:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	29 Mar 2021 19:13:17
	(b) (4)	

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.		06 Apr 2021 20:55:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	29 Mar 2021 19:13:17
	(b) (4)	

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User entered empty.	System	29 Mar 2021 19:13:17

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.		06 Apr 2021 20:55:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	29 Mar 2021 19:13:17
	(b) (4)	

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.		06 Apr 2021 20:55:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered empty.	(b) (4) Andrea Newlands (b) (4) (b) (4)	29 Mar 2021 19:13:17

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:55:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	29 Mar 2021 19:13:17
	(b) (4)	

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:55:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	29 Mar 2021 19:13:17
	(b) (4)	

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User entered empty.	System	29 Mar 2021 19:13:17

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.		06 Apr 2021 20:55:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered empty.	(b) (4) Andrea Newlands (b) (4) (b) (4)	29 Mar 2021 19:13:17

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User entered empty.	System	29 Mar 2021 19:13:17

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.		06 Apr 2021 20:55:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered empty.	(b) (4) Andrea Newlands (b) (4) (b) (4)	29 Mar 2021 19:13:17

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User entered empty.	System	29 Mar 2021 19:13:17

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.		06 Apr 2021 20:55:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered empty.	(b) (4) Andrea Newlands (b) (4) (b) (4)	29 Mar 2021 19:13:17

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User entered empty.	System	29 Mar 2021 19:13:17

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48

US3412013

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48

US3412013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.		06 Apr 2021 20:56:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:08:40

US3412013

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:56:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered empty.	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:08:40

US3412013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.		06 Apr 2021 20:56:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:09:03

US3412013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.		06 Apr 2021 20:56:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered '02 Mar 2021'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:09:03

US3412013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.		06 Apr 2021 20:56:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered '13:35'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:09:03

US3412013

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User entered '02 Mar 2021 13:35'	System	25 Mar 2021 13:09:03

US3412013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
DataPoint Verified.		06 Apr 2021 20:56:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	25 Mar 2021 13:09:11

US3412013

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	14 Apr 2021 04:46:48
User entered 'I'	System	25 Mar 2021 13:09:11

US3412013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
DataPoint Verified.		06 Apr 2021 20:54:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered 'Yes (Y)'	(b) (4)	
	Mason Urban (b) (4)	25 Mar 2021 15:30:47
	(b) (4)	

US3412013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Date of Contact or Contact Attempt \(dd MMM yyyy\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
DataPoint Verified.	(b) (4)	06 Apr 2021 20:54:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered '25 Mar 2021'	(b) (4)	
	Mason Urban (b) (4)	25 Mar 2021 15:30:47
	(b) (4)	

US3412013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
DataPoint Verified.		06 Apr 2021 20:54:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered 'Contact Made (CONTACT MADE)'	(b) (4) Mason Urban (b) (4) (b) (4)	25 Mar 2021 15:30:47

US3412013

Folder: Safety Call Day 239 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
DataPoint Verified.	(b) (4)	06 Apr 2021 20:54:04
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered empty.	(b) (4)	
	Mason Urban (b) (4)	25 Mar 2021 15:30:47
	(b) (4)	

US3412013

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:54:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered 'Yes (Y)'	Mason Urban (b) (4)	25 Mar 2021 15:30:53

US3412013

Folder: Safety Call Day 239 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'I'	System	25 Mar 2021 15:30:53

US3412013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:11:37

US3412013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:04
User entered '21 Apr 2021'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:11:37

US3412013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:04
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:11:37

US3412013

Folder: Safety Call Day 269 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:24:56

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:04
User entered empty.	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:11:37

US3412013

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:38:04
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 15:11:41

US3412013

Folder: Safety Call Day 269 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:24:56

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	21 Apr 2021 15:11:41

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:56

[Date of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:52
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:18
User entered '02 Oct 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:37:54

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:56

[Time of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:52
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	11 Dec 2020 10:36:18
DataPoint Verified.	(b) (4), (b) (6)	24 Nov 2020 01:32:10
User closed query 'Per source visit scheduled for 11:00?' (Site from CRA).	(b) (4), (b) (6)	24 Nov 2020 01:32:07
Query 'Per source visit scheduled for 11:00?' answered with 'information for time confirmed and updated' (Site from CRA).	Mylene Asmar-Rios	05 Nov 2020 19:41:50
DataPoint Un-verified.	(b) (4)	
	Mylene Asmar-Rios	05 Nov 2020 19:41:29
User entered '11:00' reason for change: Data Entry Error	(b) (4)	
	Mylene Asmar-Rios	05 Nov 2020 19:41:29
User opened query 'Per source visit scheduled for 11:00?' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:39:02
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:18
Query 'Data is required. Please complete.' answered with 'time is unknown' (Site from System).	Steven Anderson (b) (4)	02 Oct 2020 17:38:03
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
	System	02 Oct 2020 17:37:54
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:54
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:56

[Date and Time of Contact \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:52
User entered '02 Oct 2020 11:00'	System	05 Nov 2020 19:41:29
User entered empty.	System	02 Oct 2020 17:37:54

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:56

[Type of Contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:52
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:18
User entered 'Clinical Visit - Unscheduled (Clinical Visit - Unscheduled)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:37:54

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:24:56

[Has the subject reported symptoms of SARS-COV-2?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:22:52
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:18
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:54

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 2 (Day 2)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:49
User entered 'Day 1 (Day 1)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Please add 01 Oct 2020 as per source this is when symptoms started' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 01:33:06
Query 'Please add 01 Oct 2020 as per source this is when symptoms started' answered with '01 oct 2020 has been added' (Site from CRA).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:24
User opened query 'Please add 01 Oct 2020 as per source this is when symptoms started' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:40:42
DataPoint Verified.		06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:30
DataPoint Verified.		06 Oct 2020 15:48:01
User entered '02 Oct 2020'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Per CDM: It appears that O2 Saturation was not recorded. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4) (b) (4), (b) (6)	18 Jan 2021 10:06:49
Query 'Per CDM: It appears that O2 Saturation was not recorded. If not collected, please consider recording these as NOT DONE' answered with 'O2 SATURATION WAS NOT DONE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	12 Jan 2021 16:16:33
User opened query 'Per CDM: It appears that O2 Saturation was not recorded. If not collected, please consider recording these as NOT DONE' (Site from DM).	(b) (4), (b) (6)	08 Jan 2021 10:42:59
DataPoint Verified.		06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:31
DataPoint Verified.		06 Oct 2020 15:48:01
User entered '0'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:06:48
DataPoint Un-verified.	Melissa Fuson (b) (4)	12 Jan 2021 16:16:16
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4)	12 Jan 2021 16:16:16
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:33
DataPoint Verified.		06 Oct 2020 15:48:01
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User entered '%'	System	12 Jan 2021 16:16:16
User entered empty.	System	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:37
DataPoint Verified.		06 Oct 2020 15:48:01
User entered '36.9' C	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:38
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:40
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'Severe (Severe)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:41
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:44
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:46
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

Muscle Aches (Myalgia)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:47
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:49
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
DataPoint Un-verified.	Melissa Fuson (b) (4)	04 Nov 2020 15:14:46
User entered 'Mild (Mild)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 15:14:46
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:50
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'Moderate (Moderate)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:53
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'Severe (Severe)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:54
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'Severe (Severe)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:57
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'Severe (Severe)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

Runny Nose (Rhinorrhea)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
DataPoint Un-verified.	Melissa Fuson (b) (4)	04 Nov 2020 15:19:41
User entered 'None (None)' reason for change: Data Entry Error	(b) (4)	04 Nov 2020 15:19:41
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:48:58
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'Severe (Severe)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42
	(b) (4)	

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:49:00
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:49:02
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:49:04
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'None (None)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (1)

Generated On: 09 Jun 2021 17:24:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	06 Oct 2020 16:11:12
DataPoint Un-verified.		06 Oct 2020 15:49:05
DataPoint Verified.		06 Oct 2020 15:48:01
User entered 'Mild (Mild)'	Steven Anderson (b) (4)	02 Oct 2020 17:39:42

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 3 (Day 3)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:49
User entered 'Day 2 (Day 2)'	Melissa Fuson (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '03 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '97'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User entered '%'	System	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '97.7' F	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

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[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Severe (Severe)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (2)

Generated On: 09 Jun 2021 17:24:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:22:28

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 4 (Day 4)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:49
User entered 'Day 3 (Day 3)'	Melissa Fuson (b) (4)	04 Nov 2020 15:24:38

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:08
User entered '04 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:11
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:13
User entered '97'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User entered '%'	System	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:17
User entered '97.3' F	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:18
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:21
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:26
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:28
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:34
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:41
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:44
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:46
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:53
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:02:56
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:03:01
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:03:03
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:03:05
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:03:07
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:03:10
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (3)

Generated On: 09 Jun 2021 17:24:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:03:12
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:24:38

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 5 (Day 5)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:49
User entered 'Day 4 (Day 4)'	Melissa Fuson (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '05 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '98'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User entered '%'	System	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '98.2' F	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (4)

Generated On: 09 Jun 2021 17:24:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:26:44

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Day 8 (Day 8)' reason for change: Data Entry Error	(b) (4) Mylene Asmar-Rios	05 Nov 2020 20:03:35
User entered 'Day 6 (Day 6)' reason for change: Data Entry Error	(b) (4) Mylene Asmar-Rios	05 Nov 2020 19:43:49
User entered 'Day 5 (Day 5)'	(b) (4) Melissa Fuson (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '06 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

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[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '98'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User entered '%'	System	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '98.2' F	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Severe (Severe)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (5)

Generated On: 09 Jun 2021 17:24:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:29:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Day 9 (Day 9)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 7 (Day 7)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:43:49
User entered 'Day 6 (Day 6)'	Melissa Fuson (b) (4)	04 Nov 2020 15:31:13

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '07 Oct 2020'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '0'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '98'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User entered '%'	System	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered '97.4' F	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Mild (Mild)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'Moderate (Moderate)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (6)

Generated On: 09 Jun 2021 17:24:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:09:21
User entered 'None (None)'	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:31:13

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Day 3 (Day 3)' reason for change:	(b) (4)	
Data Entry Error	Mylene Asmar-Rios	05 Nov 2020 20:03:35
User entered 'Day 1 (Day 1)'	(b) (4)	
	Mylene Asmar-Rios	05 Nov 2020 19:44:05
	(b) (4)	

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered 'I'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User entered empty.	System	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (7)

Generated On: 09 Jun 2021 17:24:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:24
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 19:44:05

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Day 1 (Day 1)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:35
User entered 'Day 2 (Day 2)'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered '29 Sep 2020'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered 'l'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User entered empty.	System	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (8)

Generated On: 09 Jun 2021 17:24:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:19
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:02:46

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Symptom Day](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Day 2 (Day 2)'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Date](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered '30 Sep 2020'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Assessment Not Done](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered 'I'	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

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Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[O2 Saturation Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User entered empty.	System	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Temperature](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Shortness of Breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Difficulty Breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Muscle Aches \(Myalgia\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Body Aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[New Loss of Smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Nasal Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Runny Nose \(Rhinorrhea\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Symptom Log (9)

Generated On: 09 Jun 2021 17:24:56

[Sore Throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 20:05:17
User entered empty.	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:03:01

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:56

[Date of Visit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered '02 Oct 2020'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:40:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:56

[Was the Subject Tested For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:40:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:56

[Did Subject Test Positive For SARS-CoV-2 by RT-PCR?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:40:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:56

[Date of Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered '02 Oct 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:40:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:56

Type of Test Performed

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered 'Nasopharyngeal Swab (Nasopharyngeal Swab)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:40:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:56

[Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:40:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:56

[Was this diagnostic test performed at a lab other than the Study Central Lab?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:40:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:56

[Lab/ Institution Test Performed](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered empty.	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:40:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:56

[CLIA Certified?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:06
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Oct 2020 16:11:29
User entered empty.	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:40:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: COVID Diagnostic Test

Generated On: 09 Jun 2021 17:24:56

[COVID-19 Positive \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:06
User entered '0'	System	02 Oct 2020 17:40:10

US3412013

Folder: Covid-19 Assessment 02 Oct 2020

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:24:56

[Generate Next COVID-19 Assessment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 18:23:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:41:00
DataPoint Un-verified.	Melissa Fuson (b) (4)	04 Nov 2020 15:33:41
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	04 Nov 2020 15:33:41
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:33:01
User entered 'Yes (Y)'	Steven Anderson (b) (4)	13 Oct 2020 17:42:21

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:24:56

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 07:56:54
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'SAMPLE WAS SHIPPED ON ACCESSION NUMB ER: 1F60325' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	07 Jan 2021 19:19:52
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness Visit Day 3 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 06:07:57
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04,06OCT2020 is recorded under Illness Visit Day 3,5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		09 Dec 2020 06:43:07

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:24:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03OCT2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' canceled (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:52:08
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03OCT2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		25 Feb 2021 09:44:41
DataPoint Verified.		06 Nov 2020 22:28:58
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:24:56

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Thanks for the confirmation, however, please review the preclaus data and update the sample sent date and actual sample collection date to reflect correctly in PPD portal, confirm the same in query response.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	26 Mar 2021 05:33:52
	(b) (4), (b) (6)	16 Mar 2021 18:32:08
Query 'Per GCL Lab Reconciliation: Saliva: Thanks for the confirmation, however, please review the preclaus data and update the sample sent date and actual sample collection date to reflect correctly in PPD portal, confirm the same in query response.' answered with 'This has been updated in the preclarus portal' (Site from DM).	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:22:12
User opened query 'Per GCL Lab Reconciliation: Saliva: Thanks for the confirmation, however, please review the preclaus data and update the sample sent date and actual sample collection date to reflect correctly in PPD portal, confirm the same in query response.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:14:02
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03OCT2020 is recorded under Illness visit in EDC, however day 3 saliva is dated 09oct2020 in PPD central la, please verify and update the data in EDC or in PPD via DCF.Thanks ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:14:02
DataPoint Un-verified.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:57:08
User entered '04 Oct 2020' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:57:08
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03OCT2020 is recorded under Illness visit in EDC, however day 3 saliva is dated 09oct2020 in PPD central la, please verify and update the data in EDC or in PPD via DCF.Thanks ' answered with 'Hello this is incorrect subject collected saliva on 03-oct-2020 and it was scanned into the system 09-oct-2020' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:54:56

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:24:56

[Date of Collection](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 03OCT2020 is recorded under Illness visit in EDC, however day 3 saliva is dated 09oct2020 in PPD central la, please verify and update the data in EDC or in PPD via DCF.Thanks ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	02 Mar 2021 08:54:57
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).		25 Feb 2021 19:02:58
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'accession 1F619521068' (Site from DM). DataPoint Un-verified.	Andrea Newlands (b) (4)	17 Feb 2021 13:18:45
User entered '03 Oct 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 13:18:07
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	05 Feb 2021 05:23:54

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Folder: Illness Visit (1)

Form: Saliva Collection (1)

Generated On: 09 Jun 2021 17:24:56

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	24 Nov 2020 04:28:23
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' answered with 'DATES ARE CORRECT PER PPD SPECIMEN RECEIVED STATEMENT. DAY 3 (1F619521068) AND DAY 5(1F621099106) WERE COLLECTED AND RECEIVED THE SAME DAY) PER REQUESTION FORM SAMPLE DATA(DAY3-(03-OCT-2020) & (DAY5-(06-OCT-2020) WERE COLLECTED. RECEIVING SAMPLES COULD BE OFF DUE TO B ACKLOG' (Site from DM).	Melissa Fuson (b) (4)	16 Nov 2020 15:48:28
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 04OCT2020 is recorded under Illness Visit Day 3 visit in EDC, however the sample is reported with date 09OCT2020 in PPD Central lab. Please review and confirm the correct date and update as appropriate. Else Clarify, Thank you.' (Site from DM).	(b) (4), (b) (6)	10 Nov 2020 07:02:57
User closed query 'Please confirm collection date' (Site from CRA).	(b) (4), (b) (6)	06 Nov 2020 22:29:09
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
Query 'Please confirm collection date' answered with 'collection confirmed' (Site from CRA).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 17:41:47
User entered '04 Oct 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	05 Nov 2020 17:41:36
User opened query 'Please confirm collection date' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:49:15
User entered '03 Oct 2020'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

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EAB) (1725)

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Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:24:56

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 07:56:59
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' answered with 'SAMPLE WAS SHIPPED ON ACCESSION NUMB ER: 1F60325' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	07 Jan 2021 19:20:13
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness Visit Day 5 in EDC, however the sample is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	06 Jan 2021 06:08:07
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	09 Dec 2020 08:18:24
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'per preclaur the lab samples had been collected and processed all dates will be updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	07 Dec 2020 18:46:55

PRODUCTION RELEASE (v12.003
EAB) (1725)

2024 of 3357

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:24:56

[Visit](#)

Audit	User	Time (GMT)
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness Visits in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	02 Dec 2020 08:31:07
User accepted default value 'Day 5 (Day 5)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:24:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:24:56

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Per GCL Lab Reconciliation: Saliva: Thanks for the confirmation, however, please review the preclaus data and update the sample sent date and actual sample collection date to reflect correctly in PPD portal, confirm the same in query response.' (Site from DM).	(b) (4) (b) (4), (b) (6)	26 Mar 2021 05:34:18
Query 'Per GCL Lab Reconciliation: Saliva: Thanks for the confirmation, however, please review the preclaus data and update the sample sent date and actual sample collection date to reflect correctly in PPD portal, confirm the same in query response.' answered with 'This has been updated in the preclarus portal' (Site from DM).	Steven Anderson (b) (4) (b) (4)	16 Mar 2021 14:22:21
User opened query 'Per GCL Lab Reconciliation: Saliva: Thanks for the confirmation, however, please review the preclaus data and update the sample sent date and actual sample collection date to reflect correctly in PPD portal, confirm the same in query response.' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:14:18
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness visit in EDC, however day 3 saliva is dated 09oct2020 in PPD central la, please verify and update the data in EDC or in PPD via DCF.Thanks ? ' (Site from DM).	(b) (4), (b) (6)	16 Mar 2021 06:14:18
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness visit in EDC, however day 3 saliva is dated 09oct2020 in PPD central la, please verify and update the data in EDC or in PPD via DCF.Thanks ? ' answered with 'hello this is incorrect subject collected the saliva on 06-oct-2020 and it was scanned into the system on 09-oct-2020' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:55:54
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness visit in EDC, however day 3 saliva is dated 09oct2020 in PPD central la, please verify and update the data in EDC or in PPD via DCF.Thanks ? ' (Site from DM).	(b) (4), (b) (6)	02 Mar 2021 08:55:28

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (2)

Generated On: 09 Jun 2021 17:24:56

[Date of Collection](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 10:23:06
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.'	Andrea Newlands (b) (4)	17 Feb 2021 13:19:08
' answered with 'ACCESSION 1F621099106' (Site from DM).	(b) (4)	
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 06OCT2020 is recorded under Illness visit in EDC, however the same is missing in PPD Central lab. Please review if the sample has been shipped then provide Accession number for tracking or else, please ship the sample and provide the tracking details in the response. Thank you.'	(b) (4), (b) (6)	05 Feb 2021 05:24:43
(Site from DM).		
User closed query 'Please confirm collection date' (Site from CRA).		06 Nov 2020 22:29:03
DataPoint Verified.		06 Nov 2020 22:28:58
Query 'Please confirm collection date' answered with 'collection date confirmed' (Site from CRA).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 17:55:03
User opened query 'Please confirm collection date' (Site from CRA).	(b) (4), (b) (6)	04 Nov 2020 21:49:24
User entered '06 Oct 2020'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:24:56

[Visit](#)

Audit	User	Time (GMT)
User closed query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	19 Jan 2021 07:57:07
Query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' answered with 'the 09-oct-2020 samples were for day 3 and 5 there was not day 7 due to negative status. will update records' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	18 Jan 2021 20:52:25
User opened query 'Per GCL Lab Reconciliation: Saliva: Sample dated 09OCT2020 is reported under Illness visit in PPD Central lab, however the same is missing in EDC. Please review if the sample has been collected then update the details under appropriate visit. Else clarify, thank you. ' (Site from DM).	(b) (4), (b) (6)	11 Jan 2021 04:18:18
User accepted default value 'Day 7 (Day 7)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:24:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	27 Jan 2021 19:59:55
DataPoint Un-verified.	(b) (4), (b) (6)	
	Melissa Fuson (b) (4)	18 Jan 2021 20:52:32
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Melissa Fuson (b) (4)	18 Jan 2021 20:52:32
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'No (N)'	Mylene Asmar-Rios	04 Nov 2020 18:06:55
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (3)

Generated On: 09 Jun 2021 17:24:56

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:24:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 9 (Day 9)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:24:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 19:59:55
DataPoint Un-verified.		
	Melissa Fuson (b) (4)	18 Jan 2021 20:52:49
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Melissa Fuson (b) (4)	18 Jan 2021 20:52:49
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'No (N)'	Mylene Asmar-Rios	04 Nov 2020 18:06:55
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (4)

Generated On: 09 Jun 2021 17:24:56

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:24:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 14 (Day 14)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:24:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	27 Jan 2021 19:59:55
DataPoint Un-verified.	(b) (4), (b) (6)	
	Melissa Fuson (b) (4)	18 Jan 2021 20:52:49
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Melissa Fuson (b) (4)	18 Jan 2021 20:52:49
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'No (N)'	Mylene Asmar-Rios	04 Nov 2020 18:06:55
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (5)

Generated On: 09 Jun 2021 17:24:56

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:24:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 21 (Day 21)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:24:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	27 Jan 2021 19:59:55
DataPoint Un-verified.	(b) (4), (b) (6)	
	Melissa Fuson (b) (4)	18 Jan 2021 20:52:49
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Melissa Fuson (b) (4)	18 Jan 2021 20:52:49
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'No (N)'	Mylene Asmar-Rios	04 Nov 2020 18:06:55
	(b) (4)	

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Folder: Illness Visit (1)

Form: Saliva Collection (6)

Generated On: 09 Jun 2021 17:24:56

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:24:56

[Visit](#)

Audit	User	Time (GMT)
User accepted default value 'Day 28 (Day 28)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:24:56

[Was Saliva Collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 19:59:55
DataPoint Un-verified.		
	Melissa Fuson (b) (4)	18 Jan 2021 20:52:49
	(b) (4)	
User entered 'NA (COVID-19 Negative) (NA)'	Melissa Fuson (b) (4)	18 Jan 2021 20:52:49
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered 'No (N)'	Mylene Asmar-Rios	04 Nov 2020 18:06:55
	(b) (4)	

US3412013

Folder: Illness Visit (1)

Form: Saliva Collection (7)

Generated On: 09 Jun 2021 17:24:56

[Date of Collection](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	06 Nov 2020 22:28:58
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:55

US3412013

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:41:39
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:41:39
User entered '02 Oct 2020'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:41:39
User entered 'Clinic (Clinic)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User entered 'SICKD1'	System	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '02 Oct 2020'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '11:25'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User entered '02 Oct 2020 11:25'	System	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '167.5' cm	Mylene Asmar-Rios	04 Nov 2020 18:05:48
DataPoint set to visible.	(b) (4) System	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '87.3' kg	Mylene Asmar-Rios	04 Nov 2020 18:05:48
DataPoint set to visible.	(b) (4) System	04 Nov 2020 18:04:53

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '36.9' C	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered 'Oral (Oral)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered empty.	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '94'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User entered 'bpm'	System	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '17'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User entered 'breaths/min'	System	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '120'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User entered 'mmHg'	System	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:10
User entered '60'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User entered 'mmHg'	System	04 Nov 2020 18:05:48

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22

US3412013

Folder: Illness Visit Day 1 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:24:56

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22

US3412013

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:25
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:59

US3412013

Folder: Illness Visit Day 1 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:24:56

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:25
User entered '02 Oct 2020'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:05:59

US3412013

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:24:56

[Was Blood Sample Taken for Immunologic Assessment of SARS_COV-2 Infection?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:40
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:10

US3412013

Folder: Illness Visit Day 1 (1)

Form: Blood Sample Collection for Immunologic Assessment of SARS-CoV-2 Infection

Generated On: 09 Jun 2021 17:24:56

[Date of Collection](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 15:49:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	04 Nov 2020 21:42:40
User entered '02 Oct 2020'	Mylene Asmar-Rios (b) (4)	04 Nov 2020 18:06:10

US3412013

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

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:18
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:20:24

US3412013

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

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:18
User entered '18 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:20:24

US3412013

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

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[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 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:18
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:20:24

US3412013

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

Form: Visit Date

Generated On: 09 Jun 2021 17:24:56

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered 'UNBLND_DECIDE'	System	17 Feb 2021 13:20:24

US3412013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:56

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:25
User entered '13 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:21:02

US3412013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:56

[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 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:46:00

US3412013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:56

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:25
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:21:02

US3412013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:56

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
User entered 'AMENDMENT 6 OR LATER (AMENDMENT 6 OR LATER)' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 10:46:00

US3412013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:56

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:25
User entered '18 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:21:02

US3412013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:56

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:25
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:21:02

US3412013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:56

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:25
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:21:02

US3412013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:56

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:25
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:21:02

US3412013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:56

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:25
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:21:02

US3412013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:56

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered empty.	System	17 Feb 2021 13:21:02

US3412013

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

Form: Unblinding

Generated On: 09 Jun 2021 17:24:56

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered empty.	System	17 Feb 2021 13:21:02

US3412013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:33
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:22:25

US3412013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

Collection date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:33
User entered '18 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:22:25

US3412013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:33
User entered '12:36'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:22:25

US3412013

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '18 Jan 2021 12:36'	System	17 Feb 2021 13:22:25

US3412013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:56

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:38
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:22:34

US3412013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:38
User entered '18 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:22:34

US3412013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:56

[Collection time \(00:00 - 23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 18:57:38
User entered '12:19'	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 13:22:34

US3412013

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	26 Apr 2021 05:12:15
User entered '18 Jan 2021 12:19'	System	17 Feb 2021 13:22:34

US3412013

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:24:56

[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 15:24:54
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:41:16
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:36:22

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
User closed query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4) (b) (4), (b) (6)	17 Feb 2021 09:15:25
Query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' answered with 'not covid, causative organism unknown' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 22:14:16
User opened query 'Per MM, please confirm if this is not COVID-19. If not, update the AE term to reflect the causative organism, if known.' (Site from DM).	(b) (4), (b) (6)	01 Feb 2021 09:45:08
User closed query 'Per MM, please confirm if the subject was evaluated for COVID-19' (Site from DM).		09 Nov 2020 11:15:37
Query 'Per MM, please confirm if the subject was evaluated for COVID-19' answered with 'yes the subject was evaluated for COVID-19 and results came back negative ' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:09:00
User opened query 'Per MM, please confirm if the subject was evaluated for COVID-19' (Site from DM).	(b) (4), (b) (6)	05 Nov 2020 08:16:08
DataPoint Verified.		03 Nov 2020 17:35:29
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Upper respiratory tract infections, PT: Upper respiratory tract infection, LLT: Upper respiratory infection - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 17:38:51
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	02 Oct 2020 17:38:51
Data point term sent to Coder	System	02 Oct 2020 17:37:38
User entered 'upper respiratory infection'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '29 Sep 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User entered empty.	System	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:12:01
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).		23 Dec 2020 03:44:11
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' answered with 'UPDATED ONGOING AND ENDDATE AND OUTCOME' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:41:54
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:41:15
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:41:15
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 or if it occurs intermittently, please update the AE term to include "INTERMITTENT".' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 09:19:45
DataPoint Verified.		03 Nov 2020 17:35:29
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:12:03
DataPoint Un-verified.	Melissa Fuson (b) (4)	22 Dec 2020 19:41:15
User entered '16 Dec 2020' reason for change: Data Entry Error	(b) (4)	22 Dec 2020 19:41:15
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User entered empty.	System	02 Oct 2020 17:37:27

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Folder: Adverse Events

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[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'Grade 1/Mild (Grade 1/Mild)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

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[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

US3412013

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:23:34
User closed query 'Per CDM Query: Per CCGs page 38, AEs starting after last dose should have 'Action taken with investigational product' recorded as Not Applicable. Please update as appropriate.' (Site from DM).		06 Jan 2021 18:50:03
Query 'Per CDM Query: Per CCGs page 38, AEs starting after last dose should have 'Action taken with investigational product' recorded as Not Applicable. Please update as appropriate.' answered with 'UPDATED TO NOT APPLICABLE' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:23:53
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:23:29
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:23:29
User opened query 'Per CDM Query: Per CCGs page 38, AEs starting after last dose should have 'Action taken with investigational product' recorded as Not Applicable. Please update as appropriate.' (Site from DM).	(b) (4), (b) (6)	30 Dec 2020 13:17:40
DataPoint Verified.		03 Nov 2020 17:35:29
User entered 'None (NONE)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

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[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'I'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:12:08
DataPoint Un-verified.	Melissa Fuson (b) (4)	22 Dec 2020 19:41:15
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:41:15
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:35:29
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User entered '0'	System	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:24:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33
User entered '0'	System	02 Oct 2020 17:37:27

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Folder: Adverse Events

Form: Adverse Events (1)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:33

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

[AEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:47:45
Reviewed for Safety.		24 Nov 2020 13:02:58
User entered	System	24 Nov 2020 13:02:50
'USA-US061-2020-mRNA-1273-P301000014'		
User entered 'New'	(b) (4), (b) (6)	24 Nov 2020 13:02:50

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Folder: Adverse Events

Form: Adverse Events (2)

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[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:12:22
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis of hand - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 20:05:49
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Dec 2020 20:05:49
Data point term sent to Coder	System	22 Dec 2020 19:43:07
DataPoint Un-verified.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:42:47
Coding entries removed.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:42:47
User entered 'CELLULITIS - LEFT HAND' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:42:47
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:47:31
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Bacterial infections NEC, PT: Cellulitis, LLT: Cellulitis - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 17:49:36
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	25 Nov 2020 17:49:36
Data point term sent to Coder	System	25 Nov 2020 17:45:34
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	25 Nov 2020 17:44:46
User entered 'Cellulitis' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	25 Nov 2020 17:44:46
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Animal bite, LLT: Cat bite - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:58:00
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	23 Nov 2020 21:58:00
Data point term sent to Coder	System	23 Nov 2020 21:30:30
User entered 'Catbite'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:47:33
User entered 'Yes (Y)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:47:35
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:47:37
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

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Folder: Adverse Events

Form: Adverse Events (2)

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:47:38
User entered '20 Nov 2020'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:47:40
User entered empty.	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

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Folder: Adverse Events

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	23 Nov 2020 21:29:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
User closed query 'End date 12 Dec 2020 per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	27 Jan 2021 19:11:07
DataPoint Verified.	(b) (4)	27 Jan 2021 19:11:03
Query 'End date 12 Dec 2020 per source. Please confirm and update as appropriate' answered with 'UPDATED WITH END DATE' (Site from CRA).	Melissa Fuson (b) (4)	07 Jan 2021 19:28:59
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	07 Jan 2021 19:28:41
User entered 'Yes (Y)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	07 Jan 2021 19:24:15
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	31 Dec 2020 13:24:24
User opened query 'End date 12 Dec 2020 per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 21:12:43
DataPoint Un-verified.	(b) (4)	29 Dec 2020 21:12:29
DataPoint Verified.	(b) (4)	03 Dec 2020 15:47:41
User entered 'Yes (Y)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	(b) (4)	16 Feb 2021 22:15:22
Query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' answered by data change (Site from System).	System	16 Feb 2021 22:15:22
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:11:10
User opened query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	07 Jan 2021 19:28:41
User entered '12 Dec 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	07 Jan 2021 19:28:41
User closed query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	(b) (4)	07 Jan 2021 19:24:15
User opened query 'Ongoing is No, but End Date is missing. Please provide.' (Site from System).	System	31 Dec 2020 13:24:24
User entered empty.	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:11:15
User entered empty.	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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Generated On: 09 Jun 2021 17:24:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' canceled (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 20:30:35
User opened query 'PV Query: Please provide the event end date (recovered, returned to baseline, or, in the investigator's opinion, a new baseline has been achieved), when available. ' (Site from Safety).		01 Dec 2020 17:00:02
User entered empty.	System	23 Nov 2020 21:29:39

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[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:47:55
User entered 'Grade 4 (Grade 4)'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:47:57
User entered 'Yes (Y)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:11:21
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 19:11:23
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	16 Feb 2021 22:35:15
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered by data change (Site from System).	System	16 Feb 2021 22:35:15
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	16 Feb 2021 22:25:05
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:48:11
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4)	27 Nov 2020 04:08:44
Query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' answered with 'Subject has not been discharged yet. Therefor discharge date will still be missing' (Site from System).	Steven Anderson (b) (4)	23 Nov 2020 21:32:11
User opened query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	System	23 Nov 2020 21:29:39
User entered 'I'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:48:24
User entered '22 Nov 2020'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

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Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
User closed query 'PV Query: Please provide any medical intervention when subject met with hand surgeon and primary care physician after discharge.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	03 Mar 2021 14:00:43
Query 'PV Query: Please provide any medical intervention when subject met with hand surgeon and primary care physician after discharge.' answered with 'hand surgeon - debridement of hand during hospital stay, no medical intervention after discharge' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	26 Feb 2021 16:54:30
User opened query 'PV Query: Please provide any medical intervention when subject met with hand surgeon and primary care physician after discharge.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 22:33:32
DataPoint Verified.		25 Feb 2021 17:49:20
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).		19 Feb 2021 13:57:30
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'emailed' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	17 Feb 2021 18:56:23
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	17 Feb 2021 16:32:25
User closed query 'Per CDM: Please provide the hospital discharge date once the data is available. Leave the query open till the update is made else respond to clarify. Thank you' (Site from DM).		17 Feb 2021 09:15:51
Query 'PV Query: Please provide the hospital discharge date when available.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 22:35:26

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per CDM: Please provide the hospital discharge date once the data is available. Leave the query open till the update is made else respond to clarify. Thank you' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	16 Feb 2021 22:35:21
User entered '24 Nov 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 22:35:15
User opened query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	13 Jan 2021 19:07:51
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		07 Jan 2021 19:12:06
User opened query 'Per CDM: Please provide the hospital discharge date once the data is available. Leave the query open till the update is made else respond to clarify. Thank you' (Site from DM).		27 Nov 2020 04:08:42
User entered empty.	Steven Anderson (b) (4)	23 Nov 2020 21:29:39

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Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:49:25
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	System	16 Feb 2021 22:25:05
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 22:25:05
User closed query 'please confirm? Was subject actually in ICU?' (Site from CRA). Query 'please confirm? Was subject actually in ICU?' answered with 'it is unknown at this point if subject was actually in ICU' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 20:52:39
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	Steven Anderson (b) (4) (b) (4)	07 Dec 2020 18:41:18
User entered 'Unknown (UNK)' reason for change: Data Entry Error	System	07 Dec 2020 18:40:56
User opened query 'please confirm? Was subject actually in ICU?' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	07 Dec 2020 18:40:56
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System). Query 'Admitted to ICU? is Unknown. However, this System data must be collected. Please leave this query open until the response can be updated to Yes or No.' answered by data change (Site from System).	(b) (4), (b) (6)	03 Dec 2020 15:49:36
User entered 'Yes (Y)' reason for change: Data Entry Error	System	23 Nov 2020 21:31:36
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:31:36
	System	23 Nov 2020 21:29:39

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Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
User entered 'Unknown (UNK)'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

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Form: Adverse Events (2)

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Number of Days in ICU

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:49:27
User closed query 'PV Query: Case narrative admitted to ICU was updated from yes to unknown, however number of ICU days is 1. Please clarify if subject was indeed admitted to ICU and if not, please update case narrative section appropriately.' (Site from Safety).		17 Feb 2021 16:32:31
Query 'PV Query: Case narrative admitted to ICU was updated from yes to unknown, however number of ICU days is 1. Please clarify if subject was indeed admitted to ICU and if not, please update case narrative section appropriately.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	16 Feb 2021 22:25:20
User entered empty; reason for change Data Entry Error	(b) (4)	16 Feb 2021 22:25:05
User opened query 'PV Query: Case narrative admitted to ICU was updated from yes to unknown, however number of ICU days is 1. Please clarify if subject was indeed admitted to ICU and if not, please update case narrative section appropriately.' (Site from Safety).	(b) (4), (b) (6)	30 Dec 2020 18:39:15
User closed query 'Admitted to ICU? is Yes, however System Number of Days in ICU is missing. Please review and reconcile.' (Site from System).		23 Nov 2020 21:32:16
Query 'Admitted to ICU? is Yes, however Number of System Days in ICU is missing. Please review and reconcile.' answered by data change (Site from System).		23 Nov 2020 21:32:16
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	23 Nov 2020 21:32:16
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	(b) (4)	
	System	23 Nov 2020 21:31:36
User entered empty.	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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Form: Adverse Events (2)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 19:11:44
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 19:11:43
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	27 Jan 2021 19:11:41
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:50:02
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:50:04
User entered 'Not Related (NOT RELATED)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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Action taken with investigational product

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 20:53:03
User closed query 'please update to Not Applicable' (Site from CRA).		15 Dec 2020 20:52:25
User closed query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you' (Site from DM).		08 Dec 2020 18:51:23
User closed query 'PV Query: As the last dose of study drug was given on 26 Aug 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).		07 Dec 2020 20:45:41
Query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you' answered with 'this has been updated to NA' (Site from DM).	Steven Anderson (b) (4)	07 Dec 2020 18:41:54
Query 'PV Query: As the last dose of study drug was given on 26 Aug 2020, please update the action taken with study drug from none to not applicable.' answered with 'this has been updated to NA' (Site from Safety).	Steven Anderson (b) (4)	07 Dec 2020 18:41:42
Query 'please update to Not Applicable' answered with 'this has been updated to NA' (Site from CRA).	Steven Anderson (b) (4)	07 Dec 2020 18:41:30
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Steven Anderson (b) (4)	07 Dec 2020 18:40:56
User opened query 'PV Query: As the last dose of study drug was given on 26 Aug 2020, please update the action taken with study drug from none to not applicable.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:17:07
User opened query 'please update to Not Applicable' (Site from CRA).		03 Dec 2020 15:50:19
User opened query 'Per CDM: AE start date is after last dose, however, Action Taken with IP is recorded as None. Please review and update as appropriate. Thank you' (Site from DM).		01 Dec 2020 15:55:22
User entered 'None (NONE)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39

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[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 17:49:37
User entered '0'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39
	(b) (4)	

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Form: Adverse Events (2)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Thank you for noting subject is not taking nor has taken glycopyrrolate and calcpotriene. Both were noted in the ED notes in the medical records. Please confirm if these are concomitant medications and if so, please provide an indication if known. ' (Site from Safety).	(b) (4), (b) (6)	16 Mar 2021 16:45:00
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
Query 'PV Query: Thank you for noting subject is not taking nor has taken glycopyrrolate and calcpotriene. Both were noted in the ED notes in the medical records. Please confirm if these are concomitant medications and if so, please provide an indication if known. ' answered with 'since subject has not taken either of these than they are not con meds and will not be documented in edc nor subjects chart unless subject decides to begin taking them.' (Site from Safety).	Steven Anderson (b) (4)	15 Mar 2021 13:19:24
User opened query 'PV Query: Thank you for noting subject is not taking nor has taken glycopyrrolate and calcpotriene. Both were noted in the ED notes in the medical records. Please confirm if these are concomitant medications and if so, please provide an indication if known. ' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 13:47:01
User closed query 'PV Query: Please provide indicated use for glycopyrrolate and calcpotriene.' (Site from Safety).	(b) (4), (b) (6)	03 Mar 2021 14:01:13
Query 'PV Query: Please provide indicated use for glycopyrrolate and calcpotriene.' answered with 'subject is not taking nor has taken either of these, please clarify is applicable' (Site from Safety).	Andrea Newlands (b) (4)	02 Mar 2021 20:52:37
User opened query 'PV Query: Please provide indicated use for glycopyrrolate and calcpotriene.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 22:32:20
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:49:39
User closed query 'Per CDM re-query: Thank you for adding con meds corresponding to this AE. Per previous query, it doesn't appear to have vancomycin IV in con med page as mentioned per Narrative. Please review and add else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 09:18:01

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Query 'Per CDM re-query: Thank you for adding con meds corresponding to this AE. Per previous query, it doesn't appear to have vancomycin IV in con med page as mentioned per Narrative. Please review and add else clarify in query response.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	16 Feb 2021 22:23:06
User opened query 'Per CDM re-query: Thank you for adding con meds corresponding to this AE. Per previous query, it doesn't appear to have vancomycin IV in con med page as mentioned per Narrative. Please review and add else clarify in query response.' (Site from DM).	(b) (4), (b) (6)	23 Dec 2020 04:01:50
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. Per Narrative, STARTED ON VANCOMYCIN IV. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		23 Dec 2020 03:45:28
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Per Narrative, STARTED ON VANCOMYCIN IV. Please review and add a Con Medication as appropriate or update action taken.' answered with 'UPDATED CON MEDS' (Site from DM).	Melissa Fuson (b) (4)	22 Dec 2020 20:07:15
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. Per Narrative, STARTED ON VANCOMYCIN IV. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	10 Dec 2020 05:05:50
User entered 'I'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
User closed query 'PV Query: Please provide purulent tissue culture results when available.' (Site from Safety).	(b) (4) (b) (4), (b) (6)	04 Mar 2021 20:19:24
Query 'PV Query: Please provide purulent tissue culture results when available.' answered with 'negative' (Site from Safety).	Andrea Newlands (b) (4)	03 Mar 2021 14:29:01
User opened query 'PV Query: Please provide purulent tissue culture results when available.' (Site from Safety).	(b) (4), (b) (6)	25 Feb 2021 22:32:33
User closed query 'please check concomitant procedure box since wound debridement added to Con Proc CRF' (Site from CRA).		27 Jan 2021 19:12:11
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:12:08
Query 'please check concomitant procedure box since wound debridement added to Con Proc CRF' answered with 'CHECKED CONCOMITANT PROCEDURE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:07:28
User entered '1' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:06:36
User opened query 'please check concomitant procedure box since wound debridement added to Con Proc CRF' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 20:52:18
User entered '0'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

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[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 17:49:47
User closed query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).		17 Feb 2021 16:32:41
Query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' answered with 'recovered' (Site from Safety).	Andrea Newlands (b) (4)	16 Feb 2021 22:15:36
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Andrea Newlands (b) (4)	16 Feb 2021 22:15:22
Data Entry Error		
User opened query 'PV Query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. ' (Site from Safety).	(b) (4), (b) (6)	01 Dec 2020 17:00:36
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)'	Steven Anderson (b) (4)	23 Nov 2020 21:29:39

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 17:49:56
User entered empty.	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:28:07
User closed query 'PV Query: Please provide results of COVID-19 test. If not done, please state so in your response. ' (Site from Safety).		16 Mar 2021 16:45:31
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
Query 'PV Query: Please provide results of COVID-19 test. If not done, please state so in your response. ' answered with 'This has been updated in the narrative. But, it does not seem like the subject had any diagnostic test performed for COVID-19 per subjects medical records nothing is noted' (Site from Safety).	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 13:28:25
DataPoint Un-verified.	Steven Anderson (b) (4)	15 Mar 2021 13:27:15

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[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTICED US THROUGH E-DIARY THAT SHE HAD CONTACT WITH A MEDICAL PROVIDER. SHE WENT TO SEE HER PCP ON 20-NOV-2020 TO FOLLOW UP ON HER PERSISTENT COUGH. HE ADVISED HER ON SOME OTC MEDICATIONS TO TRY. SHE HAS YET TO TRY ANY HE RECCOMENDED. ON FRIDAY ENTRY SHE WAS BIT BY HER CAT ON HER LEFT HAND. ON SATURDAY 21NOV2020 SHE WENT TO GOOD SAM ER WITH REDNESS, SWELLING, AND PAIN IN HER LEFT HAND. SHE WAS TOLD TO WATCH AND WAIT AND RETURN IF WORSENERD. SHE RETURNED TO GOOD SAM ER ON SUNDAY 22 NOV 2020 AND ADMITTED FOR A SEVERE INFECTION IN HER LEFT HAND DUE TO CATBITE. SHE HAS BEEN STARTED ON VANCOMYCIN IV AND IS WAITING FOR CONSULT FROM A HAND SURGEON THIS AFTERNOON. HER COUGH HAS ALSO WORSENERD TODAY AND SHE IS DISCUSSING IT WITH HER HOSPITALIST TODAY. SUBJECT WAS DISCHARGED FROM HOSPITAL ON 24NOV2020. NEW MEDICATIONS INCLUDE LEVOFOXACIN, METRONIDAZOLE, OXYCODONE, AND IBUPROFEN. REGARDING CONSULT WITH HAND SURGEON, NO SURGERY WAS REQUIRED, ONLY DEBRIDEMENT OF SUBJECT'S LEFT HAND. SUBJECT WILL SCHEDULE FOLLOWUP WITH HAND SURGEON AND HAS FOLLOWUP WITH PCP ON 11DEC2020. SUBJECT FEELS SHE IS IMPROVING. AE RESOLVED: 12DEC2020 COUGH WAS DUE TO SIDE OF EFFECT OF LISINOPRIL WHICH HAS SINCE BEEN DISCONTINUED; PURULENT TISSUE CULTURE NEGATIVE; No COVID diagnostic test performed'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:27:15
reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 19:55:35

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[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide results of COVID-19 test. If not done, please state so in your response.' (Site from Safety).	(b) (4), (b) (6)	10 Mar 2021 13:47:10
User closed query 'Per DM CLR: Narrative = BIT BY HER CAT. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.		10 Mar 2021 12:35:49
' (Site from DM).		
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' canceled (Site from Safety).		09 Mar 2021 20:30:29
Query 'PV Query: Please provide start/stop dates for morphine allergy, chronic osteomyelitis, fatigue, insomnia, obesity, orthostatic hypotension, sleep apnea, tobacco use, unspecified arthropathy, anesthesia block, back surgery (laminectomyx4), cervical fusion, cervical laminectomy, cholecystectomy, cholecystectomy with/without common duct exploration, colonoscopy, gallbladder surgery, lumbar laminectomy, neck surgery, spinal cord stimulator implant, amoxicillin allergy, azithromycin allergy, seldane allergy, Glucophage allergy, and valacyclovir allergy' canceled (Site from Safety).		09 Mar 2021 20:30:25
Query 'Per DM CLR: Narrative = BIT BY HER CAT. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate.	Andrea Newlands (b) (4)	09 Mar 2021 15:09:25
' answered with 'per sub investigator, this is not a separate ae' (Site from DM).	(b) (4)	
User closed query 'PV Query: Please report the etiology of the cough, and provide results of COVID-19 test if done.' (Site from Safety).	(b) (4), (b) (6)	04 Mar 2021 20:19:18
DataPoint Un-verified.		
	Andrea Newlands (b) (4)	03 Mar 2021 14:28:53
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTICED US THROUGH E-DIARY THAT SHE HAD CONTACT WITH A MEDICAL PROVIDER. SHE WENT TO SEE HER PCP ON 20-NOV-2020 TO FOLLOW UP ON HER PERSISTENT COUGH. HE ADVISED HER ON SOME OTC MEDICATIONS TO TRY. SHE HAS YET TO TRY ANY HE RECCOMENDED. ON FRIDAY ENTRY SHE WAS BIT BY HER CAT ON HER LEFT HAND. ON SATURDAY 21NOV2020 SHE WENT TO GOOD SAM ER WITH REDNESS, SWELLING, AND PAIN IN HER LEFT HAND. SHE WAS TOLD TO WATCH AND WAIT AND RETURN IF WORSENERD. SHE RETURNED TO GOOD SAM ER ON SUNDAY 22 NOV 2020 AND ADMITTED FOR A SEVERE INFECTION IN HER LEFT HAND DUE TO CATBITE. SHE HAS BEEN STARTED ON VANCOMYCIN IV AND IS WAITING FOR CONSULT FROM A HAND SURGEON THIS AFTERNOON. HER COUGH HAS ALSO WORSENERD TODAY AND SHE IS DISCUSSING IT WITH HER HOSPITALIST TODAY. SITE WILL CALL HER TOMORROW TO CHECK IN AND OBTAIN MORE INFORMATION. SUBJECT WAS DISCHARGED FROM HOSPITAL ON 24NOV2020. NEW MEDICATIONS INCLUDE LEVOFOXACIN, METRONIDAZOLE, OXYCODONE, AND IBUPROFEN. REGARDING CONSULT WITH HAND SURGEON, NO SURGERY WAS REQUIRED, ONLY DEBRIDEMENT OF SUBJECT'S LEFT HAND. SUBJECT WILL SCHEDULE FOLLOWUP WITH HAND SURGEON AND HAS FOLLOWUP WITH PCP ON 11DEC2020. SUBJECT FEELS SHE IS IMPROVING. AE RESOLVED: 12DEC2020 cough was due to side of effect of lisinopril which has since been discontinued; purulent tissue culture negative;' reason for change: Data Entry Error	Andrea Newlands (b) (4)	(b) (4) 03 Mar 2021 14:28:53

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please report the etiology of the cough, and provide results of COVID-19 test if done. answered with 'cough was due to side of effect of lisinopril which has since been discontinued' (Site from Safety).	Andrea Newlands (b) (4)	03 Mar 2021 14:28:21
User opened query 'Per DM CLR: Narrative = BIT BY HER CAT. However, please review and verify if this should be recorded as a separate AE. If yes, ensure to record this medical condition in the AE eCRF as appropriate. '(Site from DM).	(b) (4), (b) (6)	01 Mar 2021 07:46:24
User opened query 'PV Query: Please provide start/stop dates for morphine allergy, chronic osteomyelitis, fatigue, insomnia, obesity, orthostatic hypotension, sleep apnea, tobacco use, unspecified arthropathy, anesthesia block, back surgery (laminectomyx4), cervical fusion, cervical laminectomy, cholecystectomy, cholecystectomy with/without common duct exploration, colonoscopy, gallbladder surgery, lumbar laminectomy, neck surgery, spinal cord stimulator implant, amoxicillin allergy, azithromycin allergy, seldane allergy, Glucophage allergy, and valacyclovir allergy' (Site from Safety).		25 Feb 2021 22:33:09
DataPoint Verified.		25 Feb 2021 17:50:15
User closed query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		17 Feb 2021 16:32:58
User closed query 'PV Query: Please provide further information from the hand surgeon consultation, when available. ' (Site from Safety).		17 Feb 2021 16:32:54

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	(b) (4) 16 Feb 2021 22:57:26
Query 'PV Query: Please provide further information from the hand surgeon consultation, when available. ' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	(b) (4) 16 Feb 2021 22:50:15

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

[Narrative](#)

Audit	User	Time (GMT)
User entered 'SUBJECT NOTICED US THROUGH E-DIARY THAT SHE HAD CONTACT WITH A MEDICAL PROVIDER. SHE WENT TO SEE HER PCP ON 20-NOV-2020 TO FOLLOW UP ON HER PERSISTENT COUGH. HE ADVISED HER ON SOME OTC MEDICATIONS TO TRY. SHE HAS YET TO TRY ANY HE RECCOMENDED. ON FRIDAY ENTRY SHE WAS BIT BY HER CAT ON HER LEFT HAND. ON SATURDAY 21NOV2020 SHE WENT TO GOOD SAM ER WITH REDNESS, SWELLING, AND PAIN IN HER LEFT HAND. SHE WAS TOLD TO WATCH AND WAIT AND RETURN IF WORSENERD. SHE RETURNED TO GOOD SAM ER ON SUNDAY 22 NOV 2020 AND ADMITTED FOR A SEVERE INFECTION IN HER LEFT HAND DUE TO CATBITE. SHE HAS BEEN STARTED ON VANCOMYCIN IV AND IS WAITING FOR CONSULT FROM A HAND SURGEON THIS AFTERNOON. HER COUGH HAS ALSO WORSENERD TODAY AND SHE IS DISCUSSING IT WITH HER HOSPITALIST TODAY. SITE WILL CALL HER TOMORROW TO CHECK IN AND OBTAIN MORE INFORMATION. Subject was discharged from hospital on 24Nov2020. New medications include levofloxacin, metronidazole, oxycodone, and ibuprofen. Regarding consult with hand surgeon, no surgery was required, only debridement of subject's left hand. Subject will schedule followup with hand surgeon and has followup with PCP on 11Dec2020. Subject feels she is improving. AE resolved: 12Dec2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 22:49:58
User opened query 'PV Query: Please report the etiology of the cough, and provide results of COVID-19 test if done.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:18:35
Query 'IQVIA medical query: Please report the etiology of the cough, and provide results of COVID-19 test if done.' canceled (Site from Safety).		04 Dec 2020 22:18:26

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).	(b) (4), (b) (6)	04 Dec 2020 22:12:51
User opened query 'PV Query: Please provide further information from the hand surgeon consultation, when available. ' (Site from Safety).		01 Dec 2020 17:01:38
User opened query 'IQVIA medical query: Please report the etiology of the cough, and provide results of COVID-19 test if done. ' (Site from Safety).		01 Dec 2020 17:01:02
User opened query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable. ' (Site from Safety).		01 Dec 2020 17:00:15
User entered 'Subject noticed us through e-diary that she had contact with a medical provider. She went to see her PCP on 20-Nov-2020 to follow up on her persistent cough. he advised her on some OTC medications to try. She has yet to try any he recommended. On friday entry she was bit by her cat on her left hand. on saturday 21Nov2020 she went to Good Sam ER with redness, swelling, and pain in her left hand. She was told to watch and wait and return if worsened. She returned to Good Sam ER on Sunday 22 Nov 2020 and admitted for a severe infection in her left hand due to catbite. She has been started on Vancomycin IV and is waiting for consult from a hand surgeon this afternoon. Her cough has also worsened today and she is discussing it with her hospitalist today. Site will call her tomorrow to check in and obtain more information.'	Steven Anderson (b) (4) (b) (4)	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:24:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	07 Dec 2020 18:40:56
User entered '1'	System	23 Nov 2020 21:31:36
User entered '0'	System	23 Nov 2020 21:29:39

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User coded data point as SOC: Psychiatric disorders, HLGT: Anxiety disorders and symptoms, HLT: Anxiety symptoms, PT: Anxiety, LLT: Anxiety aggravated - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:23:04
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:23:04
Data point term sent to Coder	System	03 Mar 2021 14:22:27
User entered 'worsening anxiety'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '15 Sep 2020'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User entered empty.	System	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '15 Jan 2021'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User entered empty.	System	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:57:26
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:15:58
Query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' answered with 'information has been updated ' (Site from DM).	(b) (4), (b) (6)	01 Apr 2021 18:13:04
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 18:12:40
Signature has been broken.	(b) (4), (b) (6)	01 Apr 2021 18:12:40
User entered 'Grade 2/Moderate (Grade 2/Moderate) reason for change: Data Entry Error	(b) (4), (b) (6)	01 Apr 2021 18:12:40
User opened query 'Per DM CLR: AE Grade = 1/Mild, as this condition is listed as ongoing in the Med History and the AE term indicates worsening, it is unexpected that a worsening event would = Grade 1/Mild. Please review and update the grade or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	24 Mar 2021 11:38:39
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Newlands (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'l'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User entered '0'	System	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55
User entered 'I'	System	03 Mar 2021 14:21:59

US3412013

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:24:56

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 16:41:55

US3412013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:25:36
User closed query 'please spell out attention deficit disorder' (Site from CRA).	(b) (4)	16 Mar 2021 18:25:33
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: Attention deficit disorder - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 13:45:56
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	15 Mar 2021 13:45:56
Data point term sent to Coder	System	15 Mar 2021 13:45:13
Query 'please spell out attention deficit disorder' answered with 'this has been updated to the full term' (Site from CRA).	Steven Anderson (b) (4)	15 Mar 2021 13:44:39
Coding entries removed.	(b) (4)	
	Steven Anderson (b) (4)	15 Mar 2021 13:44:09
User entered 'Attention Deficit Disorder' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	13 Mar 2021 20:00:19
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 20:00:00
User opened query 'please spell out attention deficit disorder' (Site from CRA).	(b) (4)	13 Mar 2021 19:59:53
User coded data point as SOC: Psychiatric disorders, HLGT: Cognitive and attention disorders and disturbances, HLT: Attention deficit and disruptive behaviour disorders, PT: Attention deficit hyperactivity disorder, LLT: ADD - version MedDRA\\23.0.	Coder Import (b) (4)	03 Mar 2021 14:38:57
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	(b) (4)	03 Mar 2021 14:38:57
Data point term sent to Coder	System	03 Mar 2021 14:23:29
User entered 'add'	Andrea Newlands (b) (4)	03 Mar 2021 14:22:31
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 19:59:09
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

US3412013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 19:59:11
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

US3412013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 19:59:13
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

US3412013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 19:59:18
User entered '03 Feb 2021'	Andrea Newlands (b) (4)	03 Mar 2021 14:22:31
	(b) (4)	

US3412013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 19:59:19
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 19:59:22
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 19:59:30
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	03 Mar 2021 14:22:41
Query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' answered by data change (Site from System).	System	03 Mar 2021 14:22:41
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	03 Mar 2021 14:22:31
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 19:59:32
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:57:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Un-verified.	(b) (4), (b) (6)	01 Apr 2021 18:14:01
Signature has been broken.		01 Apr 2021 18:14:01
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error		01 Apr 2021 18:14:01
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 19:59:34
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Newlands (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 19:59:36
User closed query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 14:22:41
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	03 Mar 2021 14:22:41
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	03 Mar 2021 14:22:41
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	03 Mar 2021 14:22:31
User entered empty.	Andrea Newlands (b) (4)	03 Mar 2021 14:22:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4)	03 Mar 2021 14:22:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4)	03 Mar 2021 14:22:31
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

US3412013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[None](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

US3412013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
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. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).	(b) (4), (b) (6)	05 Apr 2021 13:16:12
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Please review and add a Con Medication as appropriate or update action taken. ' answered with 'Adderall has been added to con meds ' (Site from DM).		01 Apr 2021 15:06:45
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. Please review and add a Con Medication as appropriate or update action taken. ' (Site from DM).		24 Mar 2021 11:39:05
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'I'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

US3412013

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Unknown (UNKNOWN)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:41
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Mar 2021 14:22:41

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:24:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Mar 2021 14:22:31

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Adverse event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User coded data point as SOC: Renal and urinary disorders, HLGT: Urinary tract signs and symptoms, HLT: Bladder and urethral symptoms, PT: Stress urinary incontinence, LLT: Stress incontinence - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:41:58
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	03 Mar 2021 14:41:58
Data point term sent to Coder	System	03 Mar 2021 14:25:29
User entered 'stress incontinence'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '01 Mar 2021'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Severity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Admitted to ICU?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Number of Days in ICU](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Relationship to investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Action taken with investigational product](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Not Applicable (NOT APPLICABLE)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

None

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'I'	Andrea Newlands (b) (4)	03 Mar 2021 14:24:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Concomitant Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4)	03 Mar 2021 14:24:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered '0'	Andrea Newlands (b) (4)	03 Mar 2021 14:24:55
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Outcome](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered 'Unknown (UNKNOWN)'	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Narrative](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	15 Mar 2021 15:18:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 20:00:00
User entered empty.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '0'	System	03 Mar 2021 14:24:55

US3412013

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:24:56

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	03 Mar 2021 14:24:55

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:24:56

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 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:29:30
User closed query 'Please enter all meds taken for cellulitis - per source IV vancomycin, levofloxacin, metronidazole, oxycodone, ibuprofen' (Site from CRA).		27 Jan 2021 19:29:28
Query 'Please enter all meds taken for cellulitis - per source IV vancomycin, levofloxacin, metronidazole, oxycodone, ibuprofen' answered with 'ALL HAVE BEEN ADDED TO MEDICATIONS LISTING' (Site from CRA).	Melissa Fuson (b) (4)	31 Dec 2020 13:42:41
User opened query 'Please enter all meds taken for cellulitis - per source IV vancomycin, levofloxacin, metronidazole, oxycodone, ibuprofen' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 15:53:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:57:19

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
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.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:59:22
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 16:59:22
Data point term sent to Coder	System	19 Aug 2020 16:58:59
User entered 'LISINOPRIL'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'HTN'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 16:58:54
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	16 Feb 2021 23:12:27
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	16 Feb 2021 23:12:27
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User closed query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	16 Feb 2021 23:12:27
User opened query 'Ongoing is Yes, however End date is provided. Please correct.' (Site from System).	System	16 Feb 2021 23:12:23
DataPoint Un-verified.	Andrea Newlands (b) (4)	16 Feb 2021 23:12:23
User entered '29 Dec 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Andrea Newlands (b) (4)	16 Feb 2021 23:12:23
	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios	19 Aug 2020 16:58:54
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User entered '1'	System	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User entered '1'	System	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:24:37
User entered '804 (804)'	System	19 Aug 2020 16:58:54

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: LIPID MODIFYING AGENTS, ATC: LIPID MODIFYING AGENTS, PLAIN, ATC: HMG COA REDUCTASE INHIBITORS, PRODUCT: ATORVASTATIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 17:03:28
	(b) (4)	
User coded data point as Term Coded data point by	Coder Import (b) (4)	19 Aug 2020 17:03:28
User: Coder System - version	(b) (4)	
WHODrug-Global-B3\\202003.		
Data point term sent to Coder	System	19 Aug 2020 17:02:09
User entered 'ATROVASTATIN'	Mylene Asmar-Rios	19 Aug 2020 17:01:21
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'HLD'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '40'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:01:21
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:01:21

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS USED IN DIABETES, ATC: BLOOD GLUCOSE LOWERING DRUGS, EXCL. INSULINS, ATC: SULFONYLUREAS, PRODUCT: GLIMEPIRIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:59:23
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:59:23
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 17:04:14
User entered 'GLIMEPIRIDE'	Mylene Asmar-Rios	19 Aug 2020 17:04:01
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'T2DM'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '2'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:04:01
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:04:01

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: GENITO URINARY SYSTEM AND SEX HORMONES, ATC: SEX HORMONES AND MODULATORS OF THE GENITAL SYSTEM, ATC: ESTROGENS, ATC: NATURAL AND SEMISYNTHETIC ESTROGENS, PLAIN, PRODUCT: ESTRADIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:07:20
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:07:20
Data point term sent to Coder	System	19 Aug 2020 17:06:17
User entered 'ESTRADIOL'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Oct 2020 11:07:06
Query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' answered with 'date of last menopause was listed in medical history . ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 16:09:28
User opened query 'Per DM CLR: Please note that this condition is not recorded on the Med History eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate Med History eCRF. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:23:48
DataPoint Verified.		25 Aug 2020 14:44:07
User entered 'POST-MENOPAUSE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '.5'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:05:32
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:05:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
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: PROTON PUMP INHIBITORS, PRODUCT: OMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:09:25
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 17:09:25
Data point term sent to Coder	System	19 Aug 2020 17:08:22
User entered 'OMEPRAZOLE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'GERD'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '40'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:07:29
User entered 'UN UNK 2010'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:07:29

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 17:11:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	19 Aug 2020 17:11:22
	(b) (4)	
Data point term sent to Coder	System	19 Aug 2020 17:10:31
User entered 'CLONAZEPAM'	Mylene Asmar-Rios	19 Aug 2020 17:09:36
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'ANXIETY'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '.5'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:09:36
User entered 'UN UNK 2014'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:09:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: OTHER NERVOUS SYSTEM DRUGS, ATC: ANTIVERTIGO PREPARATIONS, ATC: ANTIVERTIGO PREPARATIONS, PRODUCT: MECLOZINE, PRODUCTSYNONYM: MECLIZINE [MECLOZINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	27 Aug 2020 18:09:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	27 Aug 2020 18:09:25
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Data point term sent to Coder	System	19 Aug 2020 17:13:39
User entered 'MCLIZINE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'VERTIGO'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '25'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:13:23
User entered 'UN UNK 2015'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:13:23

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIVIRALS FOR SYSTEMIC USE, ATC: DIRECT ACTING ANTIVIRALS, ATC: NUCLEOSIDES AND NUCLEOTIDES EXCL. REVERSE TRANSCRIPTASE INHIBITORS, PRODUCT: FAMCICLOVIR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:40:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Aug 2020 06:40:28
Data point term sent to Coder	System	19 Aug 2020 17:15:44
User entered 'FAMCICLOVIR'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'FEVER BLISTERS'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '250'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:15:26
User entered 'UN UNK 2018'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:15:26

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CARDIAC THERAPY, ATC: CARDIAC STIMULANTS EXCL. CARDIAC GLYCOSIDES, ATC: ADRENERGIC AND DOPAMINERGIC AGENTS, PRODUCT: MIDODRINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Aug 2020 12:53:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 12:53:49
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Data point term sent to Coder	System	19 Aug 2020 17:18:51
User entered 'MIDODRINE'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'DYSAUTONOMIA'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '5'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:18:48
User entered 'UN UNK 2015'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Aug 2020 17:18:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
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.	Coder Import (b) (4) (b) (4)	22 Aug 2020 17:47:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Aug 2020 17:47:14
Data point term sent to Coder	System	19 Aug 2020 17:24:00
User entered 'JANUVIA'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'T2DM'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '100'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:23:38
User entered 'UN UNK 2019'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:23:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
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.	(b) (4) Coder Import (b) (4)	14 Sep 2020 23:39:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	14 Sep 2020 23:39:49
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 23:27:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Aug 2020 23:27:06
Data point term sent to Coder	System	19 Aug 2020 17:26:03
User entered 'VITAMIN D'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'GENERAL SUPPLEMENT'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '25'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
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)	12 Oct 2020 11:07:31
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 'this is what is used by patient ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	29 Sep 2020 20:55:59
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 15:24:07
DataPoint Verified.		25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:25:36
User entered 'UN UNK 2019'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:25:36

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: PREGABALIN, PRODUCTSYNONYM: LYRICA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	28 Aug 2020 11:37:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	28 Aug 2020 11:37:47
DataPoint Verified.	(b) (4), (b) (6)	25 Aug 2020 14:44:07
Data point term sent to Coder	System	19 Aug 2020 17:30:21
User entered 'LYRICA'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'DYSAUTONOMIA'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '300'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'twice daily (BID)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2015). 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 19:12:17
Query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2015). Please review and reconcile Con Med and Med History start dates as appropriate. ' answered with 'OK' (Site from DM).	Mylene Asmar-Rios (b) (4)	29 Sep 2020 21:23:35
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the Med History condition (2015). Please review and reconcile Con Med and Med History start dates as appropriate. ' (Site from DM).	(b) (4), (b) (6)	21 Sep 2020 15:24:26
DataPoint Verified.		25 Aug 2020 14:44:07
Amendment Manager: Query closed during migration process because the edit check no longer exists in target version.	System	21 Aug 2020 01:14:26
User opened query 'Medication start date is greater than 28 days prior to first IP injection. Per study guidelines, only medications that are less than or equal to 28 of first study treatment should be recorded. Please reconcile.' (Site from System).	System	19 Aug 2020 17:30:06
User entered 'UN UNK 2008'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Aug 2020 14:44:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	19 Aug 2020 17:30:06

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
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: CANAGLIFLOZIN, PRODUCTSYNONYM: INVOKANA [CANAGLIFLOZIN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 05:09:49
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Sep 2020 05:09:49
Data point term sent to Coder	System	10 Sep 2020 16:08:44
User entered 'INVOCANA'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'DMT2'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '100'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'UN UNK 2020'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	16 Feb 2021 23:01:17
User entered 'No (N)' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	16 Feb 2021 23:01:17
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	16 Feb 2021 23:01:17
User entered '29 Dec 2020' reason for change: Data Entry Error	(b) (4)	16 Feb 2021 23:01:17
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User entered '1'	System	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User entered '1'	System	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:00
User entered '804 (804)'	System	10 Sep 2020 16:08:39

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 13:21:15
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Oct 2020 13:21:15
Data point term sent to Coder	System	12 Oct 2020 13:20:22
Coding entries removed.	Mylene Asmar-Rios (b) (4)	12 Oct 2020 13:19:23
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4), (b) (4)	02 Oct 2020 12:35:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	02 Oct 2020 12:35:48
Data point term sent to Coder	System	02 Oct 2020 12:34:48
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 12:34:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:10:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	10 Sep 2020 16:10:39
Data point term sent to Coder	System	10 Sep 2020 16:09:48
User entered 'TYLENOL'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User closed query 'Per CDM re-query: Please confirm if the 'INJECTION SITE PAIN' meets the criteria for an Adverse Event and if so, ensure it is captured on the AE page as appropriate.' (Site from DM).	(b) (4)	19 Oct 2020 06:46:00
Query 'Per CDM re-query: Please confirm if the 'INJECTION SITE PAIN' meets the criteria for an Adverse Event and if so, ensure it is captured on the AE page as appropriate.' answered with 'UPDATED' (Site from DM).	Mylene Asmar-Rios (b) (4)	12 Oct 2020 13:19:31
User entered 'INJECTION SITE PAIN "SOLICITED EVENT"' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	12 Oct 2020 13:19:23
User opened query 'Per CDM re-query: Please confirm if the 'INJECTION SITE PAIN' meets the criteria for an Adverse Event and if so, ensure it is captured on the AE page as appropriate.' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:33:48
User closed query 'Per DM CLR: Please note that there is no AE or record in eDiary that matches this Con Med indication during this time frame. If the 'INJECTION SITE PAIN "AE"' is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of 'INJECTION SITE PAIN "AE"' did not meet the AE reporting and update the field of 'Was this medication taken for solicited event?' as appropriate. ' (Site from DM).	(b) (4), (b) (6)	12 Oct 2020 11:33:48

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: Please note that there is no AE or record in eDiary that matches this Con Med indication during this time frame. If the 'INJECTION SITE PAIN "AE"' is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of 'INJECTION SITE PAIN "AE"' did not meet the AE reporting and update the field of 'Was this medication taken for solicited event?' as appropriate. ' answered with 'term has been updated to solicited ae' (Site from DM).	Steven Anderson (b) (4)	02 Oct 2020 12:34:41
User entered 'INJECTION SITE PAIN "Solicited AE"' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Oct 2020 12:34:25
User opened query 'Per DM CLR: Please note that there is no AE or record in eDiary that matches this Con Med indication during this time frame. If the 'INJECTION SITE PAIN "AE"' is considered a solicited local or systemic adverse reaction, and meets any of the following criteria: results in a visit to a healthcare provider (MAAE), leads to withdrawal from the study or study vaccination, or otherwise meets the definition of an SAE, please add an entry and applicable details to the AE eCRF as appropriate. Otherwise, please confirm in query response that the solicited adverse reaction of 'INJECTION SITE PAIN "AE"' did not meet the AE reporting and update the field of 'Was this medication taken for solicited event?' as appropriate. (Site from DM).	(b) (4), (b) (6)	02 Oct 2020 05:09:39
User entered 'INJECTION SITE PAIN "AE"'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '500'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'as needed (PRN)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'UN UNK 2020'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '0'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Oct 2020 12:34:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (14)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	10 Sep 2020 16:09:32

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX COUGH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:49:07
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	24 Nov 2020 04:49:07
Data point term sent to Coder	System	03 Nov 2020 19:50:46
Coding entries removed.	Jacob sekinger (b) (4)	03 Nov 2020 19:50:19
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: COUGH AND COLD PREPARATIONS, ATC: COUGH SUPPRESSANTS AND EXPECTORANTS, COMBINATIONS, ATC: OPIUM DERIVATIVES AND EXPECTORANTS, PRODUCT: DEXTROMETHORPHAN HYDROBROMIDE;GUAIFENESIN, PRODUCTSYNONYM: MUCINEX COUGH - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 05:24:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Oct 2020 05:24:43
Data point term sent to Coder	System	02 Oct 2020 17:44:52
User entered 'mucinex cough syrup'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:50:19
User closed query 'Please type out' (Site from CRA).	(b) (4)	19 Nov 2020 19:50:16
Query 'Please type out' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	03 Nov 2020 19:50:28
User entered 'Upper respiratory Infection AE' reason for change: Data Entry Error	Jacob sekinger (b) (4)	03 Nov 2020 19:50:19
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:32
DataPoint Verified.	(b) (4)	03 Nov 2020 17:38:30
User opened query 'Please type out' (Site from CRA).	(b) (4)	03 Nov 2020 17:36:52
User entered 'URI AE'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'unk'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Please confirm dose' (Site from CRA).	(b) (4) (b) (4), (b) (6)	24 Nov 2020 01:30:58
Query 'Please confirm dose' answered with 'PATIENT DID NOT KNOW DOSAGE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	04 Nov 2020 15:52:23
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User opened query 'Please confirm dose' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:37:33
User entered 'Other (OTHER)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'none'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'other (OTHER)'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'q6hr / prn'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '29 Sep 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '0'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:37:28
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	18 Feb 2021 10:58:27
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'yes' (Site from DM).	Andrea Newlands (b) (4)	17 Feb 2021 13:26:10
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	17 Feb 2021 13:26:05
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 04:02:36
User closed query 'Please confirm and update if appropriate' (Site from CRA).	(b) (4)	24 Nov 2020 01:31:43
Query 'Please confirm and update if appropriate' answered with 'confirmed' (Site from CRA).	Jacob sekinger (b) (4)	03 Nov 2020 19:50:55
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:35
DataPoint Verified.	(b) (4)	03 Nov 2020 17:38:30
User opened query 'Please confirm and update if appropriate' (Site from CRA).	(b) (4)	03 Nov 2020 17:38:19
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	17 Feb 2021 13:26:05
User entered '02 Oct 2020' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	17 Feb 2021 13:26:05
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:45:57
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 17:45:57
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Oct 2020 17:45:57
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:44:40
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User entered empty.	System	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User entered empty.	System	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:16
User entered empty.	System	02 Oct 2020 17:44:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 20:15:34
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Nov 2020 20:15:34
Data point term sent to Coder	System	03 Nov 2020 19:51:49
Coding entries removed.	Jacob sekinger (b) (4)	03 Nov 2020 19:51:33
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: THROAT PREPARATIONS, ATC: THROAT PREPARATIONS, ATC: OTHER THROAT PREPARATIONS, PRODUCT: IBUPROFEN, PRODUCTSYNONYM: ADVIL [IBUPROFEN] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 18:15:52
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Oct 2020 18:15:52
Data point term sent to Coder	System	02 Oct 2020 17:45:54
User entered 'advil'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'No (N)'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Please type out' (Site from CRA).	(b) (4), (b) (6)	19 Nov 2020 19:50:39
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:50:29
Query 'Please type out' answered with 'updated. ' (Site from CRA).	Jacob sekinger (b) (4)	03 Nov 2020 19:51:50
User entered 'Upper respiratory infection AE' reason for change: Data Entry Error	Jacob sekinger (b) (4)	03 Nov 2020 19:51:33
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:52
User opened query 'Please type out' (Site from CRA).	(b) (4), (b) (6)	03 Nov 2020 17:38:49
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'URI AE'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '200'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'mg (mg)'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'as needed (PRN)'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered 'Oral (ORAL)'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '29 Sep 2020'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered '0'	Steven Anderson (b) (4) (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:37:28
User closed query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4)	22 Feb 2021 07:50:15
Query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	19 Feb 2021 21:37:12
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 21:37:01
User opened query 'Per DM CLR: Please review if a stop date should be recorded as the corresponding AE has resolved. If yes, please update CM stop date as applicable. Otherwise, provide clarification for continued use of medication.' (Site from DM).	(b) (4), (b) (6)	13 Jan 2021 04:02:52
User closed query 'Please confirm and update if appropriate' (Site from CRA).	(b) (4)	24 Nov 2020 01:31:12
Query 'Please confirm and update if appropriate' answered with 'confirmed' (Site from CRA).	Jacob sekinger (b) (4)	03 Nov 2020 19:51:57
DataPoint Un-verified.	(b) (4), (b) (6)	03 Nov 2020 17:39:29
User opened query 'Please confirm and update if appropriate' (Site from CRA).	(b) (4)	03 Nov 2020 17:39:27
DataPoint Verified.	(b) (4)	03 Nov 2020 17:38:30
User entered 'Yes (Y)'	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	19 Feb 2021 21:37:01
User entered '24 Oct 2020' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	19 Feb 2021 21:37:01
DataPoint Verified.	(b) (4), (b) (6)	03 Nov 2020 17:38:30
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Nov 2020 17:38:30
User closed query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:45:34
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	02 Oct 2020 17:45:34
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	02 Oct 2020 17:45:34
User opened query 'Data is required. Please complete.' (Site from System).	System	02 Oct 2020 17:45:28
User entered empty.	Steven Anderson (b) (4)	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User entered empty.	System	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User entered empty.	System	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:23
User entered empty.	System	02 Oct 2020 17:45:28

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Jan 2021 19:37:33
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	02 Jan 2021 19:37:33
Data point term sent to Coder	System	31 Dec 2020 13:33:42
Coding entries removed.	Melissa Fuson (b) (4)	31 Dec 2020 13:33:36
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 21:17:45
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 23:38:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 23:38:48
Data point term sent to Coder	System	22 Dec 2020 19:56:20
User entered 'LEVOFLOXACIN'	Melissa Fuson (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:17:48
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:25:23
User closed query 'Please correct spelling' (Site from CRA).	(b) (4)	27 Jan 2021 19:25:20
Query 'Please correct spelling' answered with 'UPDATED SPELLING OF CELLULITIS' (Site from CRA).	Melissa Fuson (b) (4)	31 Dec 2020 13:34:58
User entered 'CELLULITIS- LEFT HAND' reason for change: Data Entry Error	(b) (4)	31 Dec 2020 13:33:36
User opened query 'Please correct spelling' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 21:18:11
User entered 'CELLUULITIS - LEFT HAND'	Melissa Fuson (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:14
User entered '750'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:15
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:19
User entered 'once daily (QD)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:21
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:23
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:30
User entered '24 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:32
User entered '0'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:34
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:36
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:18:37
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User entered '1'	System	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User entered '1'	System	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:36
User entered '804 (804)'	System	22 Dec 2020 19:55:47

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Jan 2021 13:12:27
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Jan 2021 13:12:27
Data point term sent to Coder	System	31 Dec 2020 13:35:42
Coding entries removed.	Melissa Fuson (b) (4)	31 Dec 2020 13:35:27
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 21:20:06
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: IMIDAZOLE DERIVATIVES, PRODUCT: METRONIDAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 23:59:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 23:59:56
Data point term sent to Coder	System	22 Dec 2020 19:57:21
User entered 'METRONIDAZOLE'	Melissa Fuson (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:09
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:25:39
User closed query 'Please correct spelling' (Site from CRA).		27 Jan 2021 19:25:37
Query 'Please correct spelling' answered with 'UPDATED SPELLING OF CELLULITIS' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:35:32
User entered 'CELLULITIS - LEFT HAND' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:35:27
User opened query 'Please correct spelling' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 21:19:55
User entered 'CELLUULITIS - LEFT HAND'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:16
User entered '500'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:17
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:20
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Please confirm frequency - every 8 hours per source' (Site from CRA).	(b) (4)	27 Jan 2021 19:26:05
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:26:00
Query 'Please confirm frequency - every 8 hours per source' answered with 'UPDATED FREQUENCY TO EVERY EIGHT HOURS' (Site from CRA).	Melissa Fuson (b) (4)	31 Dec 2020 13:36:57
User entered 'other (OTHER)' reason for change:	(b) (4)	31 Dec 2020 13:36:30
Data Entry Error	(b) (4)	
User opened query 'Please confirm frequency - every 8 hours per source' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 21:19:45
User entered 'three times daily (TID)'	Melissa Fuson (b) (4)	22 Dec 2020 19:57:04
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:26:08
DataPoint Un-verified.	Melissa Fuson (b) (4)	31 Dec 2020 13:36:30
User entered 'EVERY EIGHT HOURS' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	31 Dec 2020 13:36:30
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 21:20:21
User entered empty.	Melissa Fuson (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:24
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:26
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:28
User entered '24 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:31
User entered '0'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:32
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:35
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:37
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User entered empty.	System	31 Dec 2020 13:36:30
User entered '3'	System	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User entered empty.	System	31 Dec 2020 13:36:30
User entered '1'	System	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:05
User entered empty.	System	31 Dec 2020 13:36:30
User entered '804 (804)'	System	22 Dec 2020 19:57:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	31 Dec 2020 20:47:22
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	31 Dec 2020 20:47:22
Data point term sent to Coder	System	31 Dec 2020 13:37:43
Coding entries removed.	Melissa Fuson (b) (4)	31 Dec 2020 13:37:16
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:55
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Dec 2020 23:05:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	(b) (4)	22 Dec 2020 23:05:48
Data point term sent to Coder	System	22 Dec 2020 19:58:24
User entered 'IBUPROFEN'	Melissa Fuson (b) (4)	22 Dec 2020 19:58:05
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:20:57
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Please correct spelling' (Site from CRA).	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:26:27
		27 Jan 2021 19:26:25
Query 'Please correct spelling' answered with 'UPDATED SPELLING OF CELLULITIS' (Site from CRA).	Melissa Fuson (b) (4)	31 Dec 2020 13:37:21
	(b) (4)	
User entered 'CELLULITIS - LEFT HAND' reason for change: Data Entry Error	Melissa Fuson (b) (4)	31 Dec 2020 13:37:16
	(b) (4)	
User opened query 'Please correct spelling' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 21:21:08
User entered 'CELLUULITIS - LEFT HAND'	Melissa Fuson (b) (4)	22 Dec 2020 19:58:05
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:12
User entered '800'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:14
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:17
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:18
User entered 'three times daily (TID)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:21
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:22
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:28
User entered '24 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:32
User entered '0'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:34
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:35
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:21:39
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User entered '3'	System	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User entered '1'	System	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:42
User entered '804 (804)'	System	22 Dec 2020 19:58:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Jan 2021 14:09:28
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Jan 2021 14:09:28
Data point term sent to Coder	System	31 Dec 2020 13:37:45
Coding entries removed.	Melissa Fuson (b) (4)	31 Dec 2020 13:37:31
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 21:21:59
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	23 Dec 2020 01:07:55
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 01:07:55
Data point term sent to Coder	System	22 Dec 2020 20:00:25
User entered 'OXYCODONE'	Melissa Fuson (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:22:02
User closed query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 20:00:08
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	22 Dec 2020 20:00:08
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:08
User opened query 'Data is required. Please complete.' (Site from System).	System	22 Dec 2020 20:00:02
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:26:47
User closed query 'Please correct spelling' (Site from CRA).	(b) (4)	27 Jan 2021 19:26:43
Query 'Please correct spelling' answered with 'UPDATED SPELLING OF CELLULITIS' (Site from CRA).	Melissa Fuson (b) (4)	31 Dec 2020 13:37:37
User entered 'CELLULITIS - LEFT HAND5' reason for change: Data Entry Error	Melissa Fuson (b) (4)	31 Dec 2020 13:37:31
User opened query 'Please correct spelling' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 21:22:11
User entered 'CELLUULITIS - LEFT HAND5'	Melissa Fuson (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:22:20
User entered '5'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:22:21
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:22:24
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:22:26
User entered 'other (OTHER)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	(b) (4), (b) (6)
User closed query 'Per source, every 4 hours as needed. Please confirm and update if appropriate' (Site from CRA).		27 Jan 2021 19:26:57
Query 'Per source, every 4 hours as needed. Please confirm and update if appropriate' answered with 'UPDATED TO EVERY FOUR HOURS AS NEEDED' (Site from CRA).		27 Jan 2021 19:26:55
User entered 'EVERY FOUR HOURS AS NEEDED' reason for change: Data Entry Error	Melissa Fuson (b) (4)	31 Dec 2020 13:38:32
User opened query 'Per source, every 4 hours as needed. Please confirm and update if appropriate' (Site from CRA).	(b) (4)	
User entered 'EVERY FOUR HOURS'	Melissa Fuson (b) (4)	31 Dec 2020 13:38:18
	(b) (4), (b) (6)	(b) (4)
		29 Dec 2020 21:22:45
	Melissa Fuson (b) (4)	22 Dec 2020 20:00:02
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:22:52
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:22:53
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:22:56
User entered '24 Nov 2020'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:22:58
User entered '0'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:23:06
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:27:08
User closed query 'Stop date 29 Nov 2020 per source. Please confirm and update as appropriate' (Site from CRA).		27 Jan 2021 19:27:06
Query 'Stop date 29 Nov 2020 per source. Please confirm and update as appropriate' answered with 'UPDATED TO 29-NOV-2020 PER SOURCE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:39:26
User entered '29 Nov 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:39:10
User opened query 'Stop date 29 Nov 2020 per source. Please confirm and update as appropriate' (Site from CRA).	(b) (4), (b) (6)	29 Dec 2020 21:23:20
User entered '3 Dec 2020'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	29 Dec 2020 21:23:22
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User entered empty.	System	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User entered empty.	System	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:26:58
User entered empty.	System	22 Dec 2020 20:00:02

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:27:19
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER ANTIBACTERIALS, ATC: GLYCOPEPTIDE ANTIBACTERIALS, PRODUCT: VANCOMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Jan 2021 12:43:26
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Jan 2021 12:43:26
Data point term sent to Coder	System	31 Dec 2020 13:41:45
User entered 'VANCOMYCIN'	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:27:22
User closed query 'Data is required. Please complete.' (Site from System).	System	07 Jan 2021 19:21:12
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	07 Jan 2021 19:21:12
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	07 Jan 2021 19:21:12
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 13:41:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:27:24
User entered 'CELLULITIS (L) HAND'	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:37:28
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).		05 Mar 2021 01:25:13
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	04 Mar 2021 16:00:55
User entered '1.25' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:52:24
User closed query 'Per CDM: Please provide missing data for this medication when it becomes available.' (Site from DM).		17 Feb 2021 09:17:34
Query 'Per CDM: Please provide missing data for this medication when it becomes available.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	16 Feb 2021 22:21:37
User entered '15' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 22:21:30
User opened query 'Per CDM: Please provide missing data for this medication when it becomes available.' (Site from DM).	(b) (4), (b) (6)	12 Jan 2021 11:41:43
User closed query 'Data is required. Please complete.' (Site from System).		12 Jan 2021 11:38:36
Query 'Data is required. Please complete.' answered with 'WAITING ON MEDICAL RECORDS FROM HOSPITAL' (Site from System).	Melissa Fuson (b) (4)	07 Jan 2021 19:22:07
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User entered empty.	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'g (g)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	04 Mar 2021 16:00:48
User entered 'mg (mg)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 22:21:30
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 11:38:38
Query 'Data is required. Please complete.' answered with 'WAITING ON MEDICAL RECORDS FROM HOSPITAL' (Site from System).	Melissa Fuson (b) (4)	07 Jan 2021 19:22:11
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 13:41:08
User entered empty.	Melissa Fuson (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'twice daily (BID)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 22:22:00
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 11:38:40
Query 'Data is required. Please complete.' answered with 'WAITING ON MEDICAL RECORDS FROM HOSPITAL' (Site from System).	Melissa Fuson (b) (4) (b) (4)	07 Jan 2021 19:22:14
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 13:41:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:27:46
User entered 'Intravenous (INTRAVENOUS)'	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered empty.	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered '22 Nov 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 22:22:00
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	07 Jan 2021 19:23:01
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	31 Dec 2020 13:41:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered '0' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 22:22:00
User entered '1' reason for change: Data Entry Error	(b) (4) Melissa Fuson (b) (4)	07 Jan 2021 19:23:01
User entered '0'	(b) (4) Melissa Fuson (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 22:22:11
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 11:38:43
Query 'Data is required. Please complete.' answered with 'WAITING ON MEDICAL RECORDS FROM HOSPITAL' (Site from System).	Melissa Fuson (b) (4)	07 Jan 2021 19:22:43
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 13:41:08
User entered empty.	Melissa Fuson (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered '24 Nov 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 22:22:00
User entered empty.	(b) (4) Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 22:22:07
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4), (b) (6)	12 Jan 2021 11:38:45
Query 'Data is required. Please complete.' answered with 'WAITING ON MEDICAL RECORDS FROM HOSPITAL' (Site from System).	Melissa Fuson (b) (4)	07 Jan 2021 19:22:47
User opened query 'Data is required. Please complete.' (Site from System).	System	31 Dec 2020 13:41:08
User entered empty.	Melissa Fuson (b) (4) (b) (4)	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User entered '2'	System	16 Feb 2021 22:22:00
User entered empty.	System	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User entered '1'	System	16 Feb 2021 22:22:00
User entered empty.	System	31 Dec 2020 13:41:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:27:25
User entered '804 (804)'	System	16 Feb 2021 22:22:00
User entered empty.	System	31 Dec 2020 13:41:08

Folder: Concomitant Medication and Vaccination (1)
Form: Prior/Concomitant Medication and Vaccination (22)
Generated On: 09 Jun 2021 17:24:56
[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Per DM CLR: Con Med JARDIANCE was added/changed on 30 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Apr 2021 13:17:25
Query 'Per DM CLR: Con Med JARDIANCE was added/changed on 30 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' answered with 'the change in medication was due to insurance issue ' (Site from DM).		01 Apr 2021 15:02:15
User opened query 'Per DM CLR: Con Med JARDIANCE was added/changed on 30 DEC 2020. Please clarify if there was a WORSENING/EXACERBATION of the medical history condition requiring a change in medications. If yes, please add the applicable AE entry or explain the reason for change in regimen. ' (Site from DM).		29 Mar 2021 10:55:42
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:15:50
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.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:12:51
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:12:51
Data point term sent to Coder	System	16 Feb 2021 23:12:21

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User entered 'jardiance'	Andrea Newlands (b) (4)	16 Feb 2021 23:11:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered 'type 2 diabetes'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered '10'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered 'once daily (QD)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:37:28
User closed query 'Per DM CLR: Please review the start date of this medication as it overlaps with INVOCANA CM#13 / (Start date UN UNK 2020 - Stop date 29 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate' (Site from DM).		10 Mar 2021 09:45:47
Query 'Per DM CLR: Please review the start date of this medication as it overlaps with INVOCANA CM#13 / (Start date UN UNK 2020 - Stop date 29 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	09 Mar 2021 15:10:20
	(b) (4)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	09 Mar 2021 15:10:15
	(b) (4)	
User entered '30 Dec 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	09 Mar 2021 15:10:15
	(b) (4)	
User opened query 'Per DM CLR: Please review the start date of this medication as it overlaps with INVOCANA CM#13 / (Start date UN UNK 2020 - Stop date 29 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:55:06
Query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with INVOCANA CM#13 / (Start date UN UNK 2020 - Stop date 29 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate.		01 Mar 2021 08:54:58
' canceled (Site from DM).		

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please review the start/stop date of this medication as it overlaps with INVOCANA CM#13 / (Start date UN UNK 2020 - Stop date 29 DEC 2020). Please consider updating dates if necessary or review if this is a duplicate. Update Con Med eCRF as appropriate. ' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 08:54:41
		25 Feb 2021 19:15:50
User entered '29 Dec 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered '0'	Andrea Newlands (b) (4)	16 Feb 2021 23:11:40
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:50
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 23:11:40

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 00:16:59
User closed query 'please correct spelling to Doxycycline' (Site from CRA).		11 Mar 2021 00:16:50
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Mar 2021 08:36:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	04 Mar 2021 08:36:55
Query 'please correct spelling to Doxycycline' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	03 Mar 2021 14:47:53
Data point term sent to Coder	System	03 Mar 2021 14:47:47
Coding entries removed.	Andrea Newlands (b) (4)	03 Mar 2021 14:47:38
User entered 'DOXYCYCLINE' reason for change:	Andrea Newlands (b) (4)	03 Mar 2021 14:47:38
Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 19:16:33
User opened query 'please correct spelling to Doxycycline' (Site from CRA).		25 Feb 2021 19:16:29
DataPoint Verified.		25 Feb 2021 19:15:57
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: TETRACYCLINES, ATC: TETRACYCLINES, PRODUCT: DOXYCYCLINE - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 23:25:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4)	16 Feb 2021 23:25:44
Data point term sent to Coder	System	16 Feb 2021 23:19:33
User entered 'doxycyclone'	Andrea Newlands (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered 'cellulitis left hand'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered '100'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered 'twice daily (BID)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered '21 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered '22 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:15:57
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User entered '2'	System	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User entered '1'	System	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:11
User entered '804 (804)'	System	16 Feb 2021 23:18:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: PHENYLPIPERIDINE DERIVATIVES, PRODUCT: FENTANYL CITRATE, PRODUCTSYNONYM: NARCO - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	17 Mar 2021 13:57:44
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Mar 2021 13:57:44
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:14
Data point term sent to Coder	System	16 Feb 2021 23:20:34
User entered 'narco'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered 'cellulitis left hand'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered '5/325'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered 'as needed (PRN)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered '21 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered '23 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:14
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User entered empty.	System	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User entered empty.	System	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:44
User entered empty.	System	16 Feb 2021 23:20:12

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User coded data point as ATC: DERMATOLOGICALS, ATC: ANTIBIOTICS AND CHEMOTHERAPEUTICS FOR DERMATOLOGICAL USE, ATC: ANTIBIOTICS FOR TOPICAL USE, ATC: OTHER ANTIBIOTICS FOR TOPICAL USE, PRODUCT: BACITRACIN;POLYMYXIN B - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:24:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:24:48
Data point term sent to Coder	System	16 Feb 2021 23:22:35
User entered 'bacitracin-polymixin B'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered 'cellulitis left hand'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:17:31
User closed query 'Per DM CLR: Please review the dose/unit to consider if no. of application would be a more appropriate response (e.g. Dose = 2, Unit = Other: Applications). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 04:19:17
Query 'Per DM CLR: Please review the dose/unit to consider if no. of application would be a more appropriate response (e.g. Dose = 2, Unit = Other: Applications). Update as appropriate, otherwise clarify. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:58:25
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:58:17
User entered '1' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:58:17
User opened query 'Per DM CLR: Please review the dose/unit to consider if no. of application would be a more appropriate response (e.g. Dose = 2, Unit = Other: Applications). Update as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:56:30
DataPoint Verified.		25 Feb 2021 19:17:20
User entered '500'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered 'Other (OTHER)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:17:33
DataPoint Un-verified.	Andrea Newlands (b) (4)	03 Mar 2021 14:58:17
User entered 'application' reason for change: Data Entry Error	(b) (4)	03 Mar 2021 14:58:17
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered 'units/gram'	Andrea Newlands (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered 'Topical (TOPICAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered '21 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered '21 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:17:20
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:40
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User entered empty.	System	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User entered empty.	System	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:30
User entered empty.	System	16 Feb 2021 23:21:35

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: PROPIONIC ACID DERIVATIVES, PRODUCT: IBUPROFEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Mar 2021 19:56:05
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	06 Mar 2021 19:56:05
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:18:20
Data point term sent to Coder	System	16 Feb 2021 23:22:35
User entered 'ibuprofen'	Andrea Newlands (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered 'cellulitis left hand'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered '800'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered 'as needed (PRN)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered '21 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered '21 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:20
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User entered empty.	System	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User entered empty.	System	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:45
User entered empty.	System	16 Feb 2021 23:22:19

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: TYLENOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:24:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:24:48
Data point term sent to Coder	System	16 Feb 2021 23:23:36
User entered 'tylenol'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered 'cellulitis left hand'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:37:28
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM). Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	05 Mar 2021 00:38:11
DataPoint Un-verified.	(b) (4)	04 Mar 2021 16:01:51
User entered '650' reason for change: Data Entry Error	Andrea Newlands (b) (4)	04 Mar 2021 16:01:43
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:57:13
DataPoint Verified.	(b) (4)	25 Feb 2021 19:18:26
User entered '600'	Andrea Newlands (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
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). Query '	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:46:59
Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' answered with 'correct - rectal suppository' (Site from DM). User opened query '	Andrea Newlands (b) (4) (b) (4)	04 Mar 2021 16:02:40
Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	01 Mar 2021 08:57:25
User entered 'Rectal (RECTAL)'	(b) (4)	25 Feb 2021 19:18:26
	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered '21 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered '21 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:26
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User entered empty.	System	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User entered empty.	System	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:32:31
User entered empty.	System	16 Feb 2021 23:23:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TDAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 16:05:28
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 16:05:28
Data point term sent to Coder	System	04 Mar 2021 16:04:06
Coding entries removed.	Andrea Newlands (b) (4)	04 Mar 2021 16:03:26
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:14:02
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: VACCINES, ATC: BACTERIAL VACCINES, ATC: PERTUSSIS VACCINES, PRODUCT: DIPHTHERIA VACCINE TOXOID;PERTUSSIS VACCINE ACELLULAR;TETANUS VACCINE TOXOID, PRODUCTSYNONYM: TDAP - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 23:24:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 23:24:48
Data point term sent to Coder	System	16 Feb 2021 23:24:37
User entered 'tdap'	Andrea Newlands (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Mar 2021 00:18:14
User closed query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).		05 Mar 2021 01:09:44
Query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	04 Mar 2021 16:03:36
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	04 Mar 2021 16:03:26
DataPoint Un-verified.	Andrea Newlands (b) (4)	03 Mar 2021 14:52:00
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	03 Mar 2021 14:52:00
User opened query 'Per DM CLR: Please review response as supplements/vitamins/contraceptives and vaccines are considered as prophylaxis. Update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:58:01
DataPoint Verified.		25 Feb 2021 19:14:26
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 00:18:19
User closed query 'Wasn't this given due to cellulitis from cat bite? Please consider updating. If leaving as General Health please consider changing prophylaxis to Yes' (Site from CRA).		11 Mar 2021 00:18:11
Query 'Wasn't this given due to cellulitis from cat bite? Please consider updating. If leaving as General Health please consider changing prophylaxis to Yes' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	04 Mar 2021 16:03:34
User entered 'cellulitis from cat bite' reason for change: Data Entry Error	Andrea Newlands (b) (4)	04 Mar 2021 16:03:26
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 19:14:41
DataPoint Verified.		25 Feb 2021 19:14:26
User opened query 'Wasn't this given due to cellulitis from cat bite? Please consider updating. If leaving as General Health please consider changing prophylaxis to Yes' (Site from CRA).		25 Feb 2021 19:05:23
User entered 'general health'	Andrea Newlands (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:05:29
User entered '0.5'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:05:32
User entered 'mL (mL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:14:26
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:14:26
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:14:26
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:14:26
User entered 'Intramuscular (INTRAMUSCULAR)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:14:26
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:14:26
User entered '21 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:14:26
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:14:26
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:14:26
User entered '21 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:14:26
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User entered empty.	System	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User entered empty.	System	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:41
User entered empty.	System	16 Feb 2021 23:24:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: CARBAPENEMS, PRODUCT: MEROPENEM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:01:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:01:58
Data point term sent to Coder	System	16 Feb 2021 23:25:37
User entered 'meropenem'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered 'cellulitis left hand'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered '1000'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered 'three times daily (TID)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered '22 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered '24 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:18:33
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User entered '3'	System	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User entered '1'	System	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:31:56
User entered '804 (804)'	System	16 Feb 2021 23:25:15

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
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)	08 Mar 2021 07:17:01
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:17:01
User closed query 'Per DM CLR: Please provide the strength of this transdermal medication in the medication name, and consider recording the number of patch instead (e.g. dose=1; unit=patch). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 01:21:31
Data point term sent to Coder	System	04 Mar 2021 16:06:29
Query 'Per DM CLR: Please provide the strength of this transdermal medication in the medication name, and consider recording the number of patch instead (e.g. dose=1; unit=patch). Review and amend as appropriate. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	04 Mar 2021 16:06:07
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	04 Mar 2021 16:05:58
User entered 'LIDOCAINE (1%)' reason for change:	Andrea Newlands (b) (4)	04 Mar 2021 16:05:58
Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please provide the strength of this transdermal medication in the medication name, and consider recording the number of patch instead (e.g. dose=1; unit=patch). Review and amend as appropriate. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:59:13
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:19:19
Data point term sent to Coder	System	16 Feb 2021 23:35:55
Data point term sent to Coder	System	16 Feb 2021 23:29:40
User entered 'lidocaine'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:28:49

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EAB) (1725)

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US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered 'cellulitis left hand'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	04 Mar 2021 16:05:58
User entered '1' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	04 Mar 2021 16:05:58
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered '10'	Andrea Newlands (b) (4)	16 Feb 2021 23:28:49
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	04 Mar 2021 16:05:58
User entered 'Other (OTHER)' reason for change:	(b) (4)	
Data Entry Error	Andrea Newlands (b) (4)	04 Mar 2021 16:05:58
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered 'mL (mL)'	Andrea Newlands (b) (4)	16 Feb 2021 23:28:49
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	04 Mar 2021 16:05:58
User entered 'patch' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	04 Mar 2021 16:05:58
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered empty.	Andrea Newlands (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered 'Other (OTHER)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:35:08
User entered 'Subcutaneous (SUBCUTANEOUS)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
Query 'Per DM CLR: Please provide the strength of this transdermal medication in the medication name, and consider recording the number of patch instead (e.g. dose=1; unit=patch). Review and amend as appropriate. ' canceled (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:59:07
User opened query 'Per DM CLR: Please provide the strength of this transdermal medication in the medication name, and consider recording the number of patch instead (e.g. dose=1; unit=patch). Review and amend as appropriate. ' (Site from DM).		01 Mar 2021 08:58:58
DataPoint Verified.		25 Feb 2021 19:19:19
User entered 'transdermal' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 23:35:08
User entered empty.	Andrea Newlands (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered '23 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered '23 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:19
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User entered empty.	System	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User entered empty.	System	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:29:59
User entered empty.	System	16 Feb 2021 23:28:49

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 15:04:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 15:04:35
Data point term sent to Coder Coding entries removed.	System (b) (4), (b) (6)	01 Apr 2021 15:03:33 01 Apr 2021 15:02:54
DataPoint Verified.		16 Mar 2021 18:37:28
User closed query 'Per CDM re-query: Thank you for adding "Worsening Anxiety" in AE eCRF. Please update the indication of con med on this form to reflect the worsening condition. ' (Site from DM).		16 Mar 2021 07:11:53
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 14:20:56
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	15 Mar 2021 14:20:56
Data point term sent to Coder	System	15 Mar 2021 13:09:51
Query 'Per CDM re-query: Thank you for adding "Worsening Anxiety" in AE eCRF. Please update the indication of con med on this form to reflect the worsening condition. ' answered with 'this term has been update per query and to reflect the AE term' (Site from DM).	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:09:28
Coding entries removed.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:09:10

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:25:03
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	04 Mar 2021 20:25:03
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 04:18:39
User opened query 'Per CDM re-query: Thank you for adding "Worsening Anxiety" in AE eCRF. Please update the indication of con med on this form to reflect the worsening condition. ' (Site from DM).		04 Mar 2021 04:18:37
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' answered with 'ae added' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:56:56
Data point term sent to Coder DataPoint Un-verified.	System Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:56:54 03 Mar 2021 14:56:33
Coding entries removed.	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:56:33
User entered 'BUSPirone' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	03 Mar 2021 14:56:33
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening ANXIETY should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:59:49

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:27:25
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: AZASPIRODECANEDIONE DERIVATIVES, PRODUCT: BUSPIRONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:33:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:33:55
Data point term sent to Coder	System	16 Feb 2021 23:32:48
User entered 'busprione'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'Worsening ANXIETY' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 13:09:10
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Mar 2021 00:09:20
DataPoint Verified.		25 Feb 2021 19:27:25
User entered 'anxiety'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered '10'	Andrea Newlands (b) (4)	16 Feb 2021 23:32:45
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered empty.	Andrea Newlands (b) (4)	16 Feb 2021 23:32:45
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered 'twice daily (BID)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 21:00:23
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
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) (6)	05 Apr 2021 13:17:15
Query 'Per DM CLR: Please review the Route as this medication is not typically administered as indicated. Please update route as appropriate. ' answered with 'information has been updated' (Site from DM).		01 Apr 2021 15:03:15
DataPoint Un-verified.		01 Apr 2021 15:02:54
User entered 'Oral (ORAL)' reason for change: Data Entry Error		01 Apr 2021 15:02:54
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).		01 Apr 2021 13:13:48
DataPoint Verified.		25 Feb 2021 19:27:25
User entered 'Intraocular (INTRAOCULAR)'	Andrea Newlands (b) (4)	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:55:35
DataPoint Un-verified.	Andrea Newlands (b) (4)	18 Mar 2021 16:16:29
User entered '04 Nov 2020' reason for change: Data Entry Error	(b) (4)	18 Mar 2021 16:16:29
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered '22 Nov 2020'	Andrea Newlands (b) (4)	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered '0'	Andrea Newlands (b) (4)	16 Feb 2021 23:32:45
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:32:57
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 23:32:57
	(b) (4)	
User entered '22 Nov 2020'	Andrea Newlands (b) (4)	16 Feb 2021 23:32:45
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:25
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 23:32:45

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	18 Mar 2021 16:18:39
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 16:18:39
Data point term sent to Coder Coding entries removed.	System Andrea Newlands (b) (4)	18 Mar 2021 16:17:36 18 Mar 2021 16:17:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:29
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: FLUOXETINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 23:34:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	16 Feb 2021 23:34:46
Data point term sent to Coder User entered 'fluoxetine'	System Andrea Newlands (b) (4)	16 Feb 2021 23:33:54 16 Feb 2021 23:33:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Feb 2021 23:33:37
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	24 Mar 2021 17:55:45
DataPoint Un-verified.	Andrea Newlands (b) (4)	18 Mar 2021 16:17:21
User entered 'worsening anxiety' reason for change:	(b) (4)	
Data Entry Error	Andrea Newlands (b) (4)	18 Mar 2021 16:17:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered 'anxiety'	Andrea Newlands (b) (4)	16 Feb 2021 23:33:37
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered '10'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:33:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:33:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered empty.	Andrea Newlands (b) (4)	16 Feb 2021 23:33:37
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	16 Feb 2021 23:33:37
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:33:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:33:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered empty.	Andrea Newlands (b) (4)	16 Feb 2021 23:33:37
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	03 Mar 2021 14:57:39
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	Andrea Newlands (b) (4)	03 Mar 2021 14:57:39
	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered '22 Nov 2020'	Andrea Newlands (b) (4)	16 Feb 2021 23:33:37
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered '0'	Andrea Newlands (b) (4)	16 Feb 2021 23:33:37
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:33:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:33:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:27:29
User entered 'No (N)'	Andrea Newlands (b) (4)	16 Feb 2021 23:33:37
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 23:33:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Feb 2021 23:33:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	16 Feb 2021 23:33:37

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	05 Mar 2021 01:22:50
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification. ' answered with 'no, med was given for management while in the hospital' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	04 Mar 2021 16:07:00
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening TYPE 2 DIABETES should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:01:16
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:31:03
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 - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 11:29:00
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 Feb 2021 11:29:00
Data point term sent to Coder	System	16 Feb 2021 23:34:54
User entered 'insulin aspart'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered 'type 2 diabetes'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered '0-12'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered 'IU (IU)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered 'three times daily (TID)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered 'Subcutaneous (SUBCUTANEOUS)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered '22 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered '24 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:03
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User entered '3'	System	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User entered '1'	System	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:22
User entered '804 (804)'	System	16 Feb 2021 23:34:43

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
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 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 11:29:00
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 Feb 2021 11:29:00
Data point term sent to Coder	System	16 Feb 2021 23:36:56
User entered 'insulin aspart'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered 'type 2 diabetes'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered '0-6'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered 'IU (IU)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered 'once daily (QD)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered 'Subcutaneous (SUBCUTANEOUS)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered '22 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered '24 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:31:08
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User entered '1'	System	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User entered '1'	System	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:08
User entered '804 (804)'	System	16 Feb 2021 23:36:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: MACROLIDES, LINCOSAMIDES AND STREPTOGRAMINS, ATC: LINCOSAMIDES, PRODUCT: CLINDAMYCIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:39:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:39:42
Data point term sent to Coder	System	16 Feb 2021 23:37:56
User entered 'clindamycin'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered 'cellulitis left hand'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered '600'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User closed query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	16 Feb 2021 23:37:23
Query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' answered by data change (Site from System).	System	16 Feb 2021 23:37:23
User opened query 'Frequency is reported as Once, however the Medication Start and Stop dates are not equal. Please update or clarify.' (Site from System).	System	16 Feb 2021 23:37:13
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered '22 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered '22 Nov 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	16 Feb 2021 23:37:23
User entered '24 Nov 2020'	(b) (4) Andrea Newlands (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:49
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User entered empty.	System	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User entered empty.	System	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:35:10
User entered empty.	System	16 Feb 2021 23:37:13

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:08:58
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 12:08:58
Data point term sent to Coder	System	16 Feb 2021 23:38:57
User entered 'oxycodone'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User closed query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 23:38:26
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Feb 2021 23:38:26
User entered 'cellulitis left hand' reason for change:	Andrea Newlands (b) (4)	16 Feb 2021 23:38:26
Data Entry Error	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	16 Feb 2021 23:38:08
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered '5'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered 'as needed (PRN)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered '22 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered '24 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:44
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User entered empty.	System	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User entered empty.	System	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:53
User entered empty.	System	16 Feb 2021 23:38:08

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: NATURAL OPIUM ALKALOIDS, PRODUCT: HYDROMORPHONE HYDROCHLORIDE, PRODUCTSYNONYM: DILAUDID - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:41:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:41:47
Data point term sent to Coder	System	16 Feb 2021 23:39:57
User entered 'dilauded'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered 'cellulitis left hand'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered 'l'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered 'as needed (PRN)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered '22 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered '23 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:19:38
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User entered empty.	System	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User entered empty.	System	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:32
User entered empty.	System	16 Feb 2021 23:39:18

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	05 Mar 2021 01:24:06
DataPoint Un-verified.		05 Mar 2021 00:10:49
DataPoint Verified.		05 Mar 2021 00:10:44
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification. ' answered with 'no, med was given for management while in the hospital' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	04 Mar 2021 16:07:12
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history condition worsened. If yes, please review if an AE of Worsening GERD should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:05:56
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR ACID RELATED DISORDERS, ATC: ANTACIDS, ATC: CALCIUM COMPOUNDS, PRODUCT: CALCIUM CARBONATE, PRODUCTSYNONYM: TUMS [CALCIUM CARBONATE] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:41:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:41:47
Data point term sent to Coder	System	16 Feb 2021 23:40:58

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
User entered 'tums'	Andrea Newlands (b) (4)	16 Feb 2021 23:40:20
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'gerd'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered '1000'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'as needed (PRN)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered '23 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered '23 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User entered empty.	System	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User entered empty.	System	16 Feb 2021 23:40:20

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:54
User entered empty.	System	16 Feb 2021 23:40:20

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 15:09:04
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Mar 2021 15:09:04
Data point term sent to Coder Coding entries removed.	System Andrea Newlands (b) (4)	09 Mar 2021 15:08:28 09 Mar 2021 15:08:17
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	03 Mar 2021 15:14:06
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	03 Mar 2021 15:14:06
Data point term sent to Coder Coding entries removed.	System Andrea Newlands (b) (4)	03 Mar 2021 15:08:10 03 Mar 2021 15:07:28
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: SENNOSIDE A+B, PRODUCTSYNONYM: SENOKOT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:43:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	16 Feb 2021 23:43:42

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	16 Feb 2021 23:42:59
User entered 'senokot'	Andrea Newlands (b) (4)	16 Feb 2021 23:42:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	09 Mar 2021 15:08:17
User entered 'No (N)'	(b) (4) Andrea Newlands (b) (4)	16 Feb 2021 23:42:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:37:28
User closed query 'Per CDM re-query: Response indicates 'updated'; However there is no AE of this indication in the AE eCRF. Please add the AE as appropriate else clarify. ' (Site from DM).		10 Mar 2021 09:46:40
Query 'Per CDM re-query: Response indicates 'updated'; However there is no AE of this indication in the AE eCRF. Please add the AE as appropriate else clarify. ' answered with 'indication was updated and has been updated again' (Site from DM).	Andrea Newlands (b) (4)	09 Mar 2021 15:08:44
User entered 'prevention of CONSTIPATION AS SIDE EFFECT TO MEDS GIVEN IN HOSPITAL' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	09 Mar 2021 15:08:17
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Mar 2021 04:23:33
User opened query 'Per CDM re-query: Response indicates 'updated'; However there is no AE of this indication in the AE eCRF. Please add the AE as appropriate else clarify. ' (Site from DM).		04 Mar 2021 04:23:30
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	03 Mar 2021 15:07:46
User entered 'CONSTIPATION as side effect to meds given in hospital' reason for change: Data Entry Error	(b) (4)	
User opened query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this time frame. Please review Con Med use and add a medical condition and all applicable details to the AE eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:08:10

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User entered 'constipation'	Andrea Newlands (b) (4)	16 Feb 2021 23:42:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:37:28
User closed query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).		05 Mar 2021 01:11:36
Query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' answered with 'updated	Andrea Newlands (b) (4)	04 Mar 2021 16:14:26
' (Site from DM).	(b) (4)	
User entered '8.6' reason for change: Data Entry Error	Andrea Newlands (b) (4)	04 Mar 2021 16:14:09
	(b) (4)	
User opened query 'Per DM CLR: Please review the dose recorded as this is not the standard dose for this medication. Please correct the dosage or provide explanation for alternate dosage.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:07:25
User entered '8.5-50'	Andrea Newlands (b) (4)	16 Feb 2021 23:42:05
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:42:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:42:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'as needed (PRN)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:42:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:42:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:42:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:42:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered '22 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:42:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:42:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:42:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User entered '24 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:42:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
User closed query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).		05 Mar 2021 01:13:17
Query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	04 Mar 2021 16:14:38
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	04 Mar 2021 16:14:33
User opened query 'Per DM CLR: Was this medication taken for solicited event?' = Yes, but the Indication does not reflect one of the Solicited Events for the study (Fever, Injection Site Pain, Redness At Injection Site (Erythema), Headache, Fatigue, Chills, Nausea/Vomiting, Underarm Gland Swelling or Tenderness, Swelling/Hardness at Injection Site, Joint Aches in Several Joints, Muscle Aches All Over Body,). Please review and update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:07:38
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	16 Feb 2021 23:42:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User entered empty.	System	16 Feb 2021 23:42:05

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User entered empty.	System	16 Feb 2021 23:42:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:40
User entered empty.	System	16 Feb 2021 23:42:05

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
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)	15 Mar 2021 07:54:53
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	15 Mar 2021 07:54:53
DataPoint Verified.	(b) (4), (b) (6)	11 Mar 2021 00:22:34
User closed query 'please correct spelling Heparin' (Site from CRA).		11 Mar 2021 00:22:28
Data point term sent to Coder	System	09 Mar 2021 15:12:31
Coding entries removed.	Andrea Newlands (b) (4)	09 Mar 2021 15:12:14
User entered 'HEPARIN (5000 units/ml)' reason for change: Data Entry Error	(b) (4)	
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: VASOPROTECTIVES, ATC: ANTIVARICOSE THERAPY, ATC: HEPARINS OR HEPARINOIDS FOR TOPICAL USE, PRODUCT: HEPARIN - version WHODrug-Global-B3\\202003.	Andrea Newlands (b) (4)	09 Mar 2021 15:12:14
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	04 Mar 2021 20:59:11
Data point term sent to Coder	System	03 Mar 2021 15:10:11
Query 'please correct spelling Heparin' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	03 Mar 2021 15:10:04
Coding entries removed.	Andrea Newlands (b) (4)	03 Mar 2021 15:09:56
User entered 'HEPARIn' reason for change: Data Entry Error	Andrea Newlands (b) (4)	03 Mar 2021 15:09:56
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:24
DataPoint Verified.		25 Feb 2021 19:23:18

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User opened query 'please correct spelling Heparin' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 19:23:04
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)	18 Feb 2021 08:44:48
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 08:44:48
Data point term sent to Coder	System	16 Feb 2021 23:43:59
User entered 'heparim'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered 'cellulitis left hand'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	09 Mar 2021 15:12:14
User entered '1' reason for change: Data Entry Error	(b) (4) Andrea Newlands (b) (4)	09 Mar 2021 15:12:14
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered '5000'	Andrea Newlands (b) (4)	16 Feb 2021 23:43:16
	(b) (4)	

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	09 Mar 2021 15:12:14
User entered 'mL (mL)' reason for change: Data Entry Error	(b) (4)	09 Mar 2021 15:12:14
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	16 Feb 2021 23:43:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:37:28
DataPoint Un-verified.	Andrea Newlands (b) (4)	09 Mar 2021 15:12:14
User entered empty; reason for change Data Entry Error	(b) (4) Andrea Newlands (b) (4)	09 Mar 2021 15:12:14
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered 'units/ml'	Andrea Newlands (b) (4)	16 Feb 2021 23:43:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered 'as needed (PRN)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered 'Subcutaneous (SUBCUTANEOUS)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered '22 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered '24 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:18
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User entered empty.	System	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User entered empty.	System	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:34:25
User entered empty.	System	16 Feb 2021 23:43:16

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: QUINOLONE ANTIBACTERIALS, ATC: FLUOROQUINOLONES, PRODUCT: LEVOFLOXACIN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 11:55:59
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	17 Feb 2021 11:55:59
Data point term sent to Coder	System	16 Feb 2021 23:45:02
User entered 'levofloxacin'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered 'cellulitis left hand'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered '750'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered 'once (ONCE)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered '23 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered '0'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered '23 Nov 2020'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:03:42
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User entered empty.	System	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User entered empty.	System	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 19:33:19
User entered empty.	System	16 Feb 2021 23:44:04

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: DERMATOLOGICALS, ATC: CORTICOSTEROIDS, DERMATOLOGICAL PREPARATIONS, ATC: CORTICOSTEROIDS, PLAIN, ATC: CORTICOSTEROIDS, POTENT (GROUP III), PRODUCT: FLUOCINONIDE, PRODUCTSYNONYM: LIDEX - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 08:52:46
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	18 Mar 2021 08:52:46
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:29:30
Data point term sent to Coder	System	15 Mar 2021 13:11:52
DataPoint Un-verified.	Steven Anderson (b) (4)	15 Mar 2021 13:10:55
User entered 'LIDEX 0.05%' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 13:10:55
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:54
Data point term sent to Coder	System	16 Feb 2021 23:47:05
User entered 'lidex'	Andrea Newlands (b) (4)	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:54
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:28
User closed query 'Eczema is not on Med History CRF - please add' (Site from CRA).	(b) (4)	05 Mar 2021 00:07:25
Query 'Eczema is not on Med History CRF - please add' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	03 Mar 2021 15:16:59
Query 'Per DM CLR: Please note that this condition is not recorded on the MH eCRF. Please review Con Med use and add a medical condition and all applicable details to the appropriate MH eCRF.' canceled (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:09:46
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).		01 Mar 2021 09:09:35
User opened query 'Eczema is not on Med History CRF - please add' (Site from CRA).		25 Feb 2021 19:29:39
DataPoint Un-verified.		25 Feb 2021 19:29:19
DataPoint Verified.		25 Feb 2021 19:23:54
User entered 'eczema'	Andrea Newlands (b) (4)	16 Feb 2021 23:46:53
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:29:44
User closed query 'Per DM CLR: Note, 0.05% is a concentration/strengths, please update medication name to include this concentration/strengths and update dose and dose unit with the number of applications administered (eg, Dose-1, Dose Unit-Application). Update as appropriate.' (Site from DM).		16 Mar 2021 07:12:08
Query 'Per DM CLR: Note, 0.05% is a concentration/strengths, please update medication name to include this concentration/strengths and update dose and dose unit with the number of applications administered (eg, Dose-1, Dose Unit-Application). Update as appropriate.' answered with 'the concentration has been added to the name and the dose administration has been changed to reflect 1 application PRN' (Site from DM).	Steven Anderson (b) (4)	15 Mar 2021 13:11:29
User entered '1' reason for change: Data Entry Error	(b) (4)	15 Mar 2021 13:10:55
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:54
User opened query 'Per DM CLR: Note, 0.05% is a concentration/strengths, please update medication name to include this concentration/strengths and update dose and dose unit with the number of applications administered (eg, Dose-1, Dose Unit-Application). Update as appropriate.' (Site from DM).		01 Mar 2021 09:09:03
DataPoint Verified.		25 Feb 2021 19:23:54
User entered '0.05'	Andrea Newlands (b) (4)	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:29:47
DataPoint Un-verified.		05 Mar 2021 00:07:56
DataPoint Verified.		25 Feb 2021 19:23:54
User entered 'Other (OTHER)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:29:49
User entered 'application' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 13:10:55
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 00:07:58
DataPoint Verified.		25 Feb 2021 19:23:54
User entered '%'	Andrea Newlands (b) (4)	16 Feb 2021 23:46:53
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:54
User entered 'as needed (PRN)' reason for change:	Andrea Newlands (b) (4)	19 Feb 2021 21:37:39
Data Entry Error	(b) (4)	
User entered 'twice daily (BID)'	Andrea Newlands (b) (4)	16 Feb 2021 23:46:53
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:54
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:54
User entered 'Topical (TOPICAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:54
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:54
User entered 'un UNK 2016'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:23:54
User entered '0'	Andrea Newlands (b) (4)	16 Feb 2021 23:46:53
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:54
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:54
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:54
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 21:37:39
User entered '2'	System	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 21:37:39
User entered '1'	System	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 21:37:39
User entered '804 (804)'	System	16 Feb 2021 23:46:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: OTHER HYPNOTICS AND SEDATIVES, PRODUCT: HYOSCINE, PRODUCTSYNONYM: SCOPOLAMINE [HYOSCINE] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	19 Mar 2021 10:57:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Mar 2021 10:57:30
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:23:59
Data point term sent to Coder	System	16 Feb 2021 23:48:06
User entered 'scopolamine'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered 'dysautonomia'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered 'I'	Andrea Newlands (b) (4)	16 Feb 2021 23:47:53
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered 'mg (mg)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered empty.	Andrea Newlands (b) (4)	16 Feb 2021 23:47:53
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	16 Feb 2021 23:47:53
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered empty.	Andrea Newlands (b) (4)	16 Feb 2021 23:47:53
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered 'Transdermal (TRANSDERMAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered 'un UNK 2017'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered '0'	Andrea Newlands (b) (4)	16 Feb 2021 23:47:53
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:23:59
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 23:47:53

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	16 Mar 2021 18:30:33
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 10:59:43
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Mar 2021 10:59:43
	(b) (4)	
Data point term sent to Coder DataPoint Un-verified.	System	09 Mar 2021 15:13:35
	Andrea Newlands (b) (4)	09 Mar 2021 15:13:02
	(b) (4)	
Coding entries removed.	Andrea Newlands (b) (4)	09 Mar 2021 15:13:02
	(b) (4)	
User entered 'DICLOFENAC GEL 1%' reason for change: Data Entry Error DataPoint Verified.	Andrea Newlands (b) (4)	09 Mar 2021 15:13:02
	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:08:24
User closed query 'please correct spelling Diclofenac gel' (Site from CRA).		05 Mar 2021 00:08:22
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 15:21:59
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	03 Mar 2021 15:21:59
	(b) (4)	
Query 'please correct spelling Diclofenac gel' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	03 Mar 2021 15:21:21
	(b) (4)	
Data point term sent to Coder	System	03 Mar 2021 15:21:14

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Name of Medication](#)

Audit	User	Time (GMT)
Coding entries removed.	Andrea Newlands (b) (4)	03 Mar 2021 15:20:51
Coding entries removed.	Andrea Newlands (b) (4)	03 Mar 2021 15:20:51
User entered 'DICLOFENAC GEL' reason for change: Data Entry Error	Andrea Newlands (b) (4)	03 Mar 2021 15:20:51
User opened query 'please correct spelling Diclofenac gel' (Site from CRA).	(b) (4), (b) (6)	25 Feb 2021 19:25:18
DataPoint Un-verified.	(b) (4), (b) (6)	25 Feb 2021 19:25:00
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:24:50
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: TOPICAL PRODUCTS FOR JOINT AND MUSCULAR PAIN, ATC: ANTIINFLAMMATORY PREPARATIONS, NON-STEROIDS FOR TOPICAL USE, PRODUCT: DICLOFENAC - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	18 Feb 2021 23:51:04
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 Feb 2021 23:51:04
Data point term sent to Coder	System	16 Feb 2021 23:49:07
User entered 'diclotenac gel'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	05 Mar 2021 00:08:31
User closed query 'please spell out chronic low back pain' (Site from CRA).		05 Mar 2021 00:08:29
Query 'please spell out chronic low back pain' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4)	03 Mar 2021 15:21:25
User entered 'chronic low back pain' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	03 Mar 2021 15:20:51
User opened query 'please spell out chronic low back pain' (Site from CRA).	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:25:48
DataPoint Un-verified.		25 Feb 2021 19:25:23
DataPoint Verified.		25 Feb 2021 19:24:50
User entered 'clbp'	Andrea Newlands (b) (4)	16 Feb 2021 23:48:50
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 19:56:51
User closed query 'Per DM CLR: Please note, 1% appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., DICLOTENAC GEL 1%) and update dose and dose unit with the number of applications for this topical medication (eg, dose= 1, dose unit= application). Update as appropriate. ' (Site from DM).		10 Mar 2021 09:46:52
Query 'Per DM CLR: Please note, 1% appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., DICLOTENAC GEL 1%) and update dose and dose unit with the number of applications for this topical medication (eg, dose= 1, dose unit= application). Update as appropriate. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	09 Mar 2021 15:13:40
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:44
User opened query 'Per DM CLR: Please note, 1% appears to be a concentration/strength, rather than dosage. Please update the Con Med entry to provide the concentration/strength in the Medication field (e.g., DICLOTENAC GEL 1%) and update dose and dose unit with the number of applications for this topical medication (eg, dose= 1, dose unit= application). Update as appropriate. ' (Site from DM).		01 Mar 2021 09:10:56
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered '1'	Andrea Newlands (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 19:56:46
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:42
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	16 Feb 2021 23:48:50
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 19:56:49
User entered 'application' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	09 Mar 2021 15:13:02
DataPoint Un-verified.	(b) (4), (b) (6)	05 Mar 2021 00:08:39
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered '%'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered 'as needed (PRN)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered 'Topical (TOPICAL)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered 'un UNK 2018'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered '0'	Andrea Newlands (b) (4)	16 Feb 2021 23:48:50
	(b) (4)	

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered empty.	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:24:50
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	16 Feb 2021 23:48:50

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

Name of Medication

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: AMFETAMINE ASPARTATE;AMFETAMINE SULFATE;DEXAMFETAMINE SACCHARATE;DEXAMFETAMINE SULFATE, PRODUCTSYNONYM: ADDERALL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	01 Apr 2021 15:07:40
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	01 Apr 2021 15:07:40
Data point term sent to Coder	System	01 Apr 2021 15:06:37
User entered 'Adderall'	(b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Prophylaxis](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Attention deficit disorder' reason for change: Data Entry Error	(b) (4)	01 Apr 2021 15:06:14
User entered 'ADD'	(b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Dose per administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered '20'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Dose unit](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'mg (mg)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[If dose unit is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Frequency](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'once daily (QD)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Route of administration](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Oral (ORAL)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered '3 Feb 2021'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Start date completely unknown](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered '0'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered empty.	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	06 Apr 2021 20:58:28
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User entered 'No (N)'	(b) (4) (b) (4), (b) (6)	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:24:56

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	01 Apr 2021 15:05:38

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:24:56

[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 14:57:47
User closed query 'please consider changing to ye and adding wound debridement of left hand as noted in source as treatment for cellulitis of left hand' (Site from CRA).	(b) (4), (b) (6)	15 Dec 2020 20:54:34
DataPoint Verified.		15 Dec 2020 20:54:30
Query 'please consider changing to ye and adding wound debridement of left hand as noted in source as treatment for cellulitis of left hand' answered with 'this has been updated with term. any new information will be updated when medical records return' (Site from CRA).	Steven Anderson (b) (4)	07 Dec 2020 18:51:56
DataPoint Un-verified.	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Steven Anderson (b) (4)	07 Dec 2020 18:48:34
User opened query 'please consider changing to ye and adding wound debridement of left hand as noted in source as treatment for cellulitis of left hand' (Site from CRA).	(b) (4), (b) (6)	03 Dec 2020 15:54:36
DataPoint Verified.		03 Nov 2020 17:41:25
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	10 Sep 2020 16:10:23

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	15 Dec 2020 20:51:10
User entered '23 Nov 2020'	Steven Anderson (b) (4)	07 Dec 2020 18:51:18
	(b) (4)	

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
User closed query 'Per ETRTR, If this concomitant procedure is related to SAE Cellulitis of 20 Nov 2020, please ensure concomitant procedure box is checked in AE page.' (Site from CRA).	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:29:52
Query 'Per ETRTR, If this concomitant procedure is related to SAE Cellulitis of 20 Nov 2020, please ensure concomitant procedure box is checked in AE page.' answered with 'CHECKED CONCOMITANT PROCEDURE IN AE' (Site from CRA).	Melissa Fuson (b) (4) (b) (4)	22 Dec 2020 20:10:13
DataPoint Verified.	(b) (4), (b) (6)	15 Dec 2020 20:51:12
User opened query 'Per ETRTR, If this concomitant procedure is related to SAE Cellulitis of 20 Nov 2020, please ensure concomitant procedure box is checked in AE page.' (Site from CRA).		07 Dec 2020 23:44:05
User entered 'Wound debridement of left hand'	Steven Anderson (b) (4) (b) (4)	07 Dec 2020 18:51:18

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:51:13
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	07 Dec 2020 18:51:18

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:24:56

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	15 Dec 2020 20:51:15
User entered empty.	Steven Anderson (b) (4) (b) (4)	07 Dec 2020 18:51:18

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:24:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:43
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered '21 Nov 2020'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:47:23

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:24:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:43
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'x-ray left writs'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:47:23

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:43
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:47:23

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:24:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:43
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:47:23

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:24:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered '22 Nov 2020'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:47:47

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:24:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'BAMP'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:47:47

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:47:47

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:24:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:45
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:47:47

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:24:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered '22 Nov 2020'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:48:12

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:24:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'cbc'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:48:12

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:48:12

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:24:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:46
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:48:12

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:24:56

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered '22 Nov 2020'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:48:46

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:24:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'c-reactive protein'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:48:46

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:48:46

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:24:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:48
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:48:46

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:24:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered '22 Nov 2020'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:49:11

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:24:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'Lactate'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:49:11

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:49:11

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:24:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:51
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:49:11

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:24:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered '23 Nov 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	15 Mar 2021 13:50:54
User entered '22 Nov 2020'	(b) (4) Steven Anderson (b) (4)	15 Mar 2021 13:49:28

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:24:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'CBC'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:49:28

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:49:28

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:24:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:53
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:49:28

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:24:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:55
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered '22 Nov 2020'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:50:03

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:24:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:55
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'Blood Culture'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:50:03

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:55
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:50:03

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:24:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:55
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:50:03

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:24:56

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered '24 Nov 2020'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:50:32

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:24:56

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'HbA1c'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:50:32

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:24:56

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered 'Adverse Event (AE)'	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:50:32

US3412013

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:24:56

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:38:58
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:57:47
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:31:41
User entered empty.	Steven Anderson (b) (4) (b) (4)	15 Mar 2021 13:50:32

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:24:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
User entered '24/Nov/2020 08:03'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	30 Nov 2020 15:05:46
User entered '1'		24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:24:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
User entered '30/Nov/2020 15:06'	System	30 Nov 2020 15:06:02

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		02 Dec 2020 14:31:51
User entered '1'		30 Nov 2020 15:06:02

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:24:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
User entered '02/Dec/2020 14:32'	System	02 Dec 2020 14:32:02

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
Reviewed for Safety.	(b) (4)	07 Dec 2020 20:45:12
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
User entered '1'		02 Dec 2020 14:32:02

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:24:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:24:12
User entered '07/Dec/2020 20:45'	System	07 Dec 2020 20:45:23

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:24:12
Reviewed for Safety.		23 Dec 2020 13:23:45
User entered '1'		07 Dec 2020 20:45:23

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:24:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:24:12
User entered '23/Dec/2020 08:23'	System	23 Dec 2020 13:24:00

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	27 Jan 2021 19:24:12
Reviewed for Safety.		04 Jan 2021 18:33:45
User entered '1'		23 Dec 2020 13:24:00

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:24:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:24:12
User entered '04/Jan/2021 18:33'	System	04 Jan 2021 18:33:51

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	27 Jan 2021 19:24:12
Reviewed for Safety.	(b) (4), (b) (6)	07 Jan 2021 20:09:13
User entered '1'		04 Jan 2021 18:33:51

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:24:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	27 Jan 2021 19:24:12
User entered '07/Jan/2021 15:09'	System	07 Jan 2021 20:09:33

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
Reviewed for Safety.	(b) (4), (b) (6)	17 Feb 2021 16:35:23
DataPoint Verified.		27 Jan 2021 19:24:12
User entered '1'		07 Jan 2021 20:09:33

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:24:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	25 Feb 2021 19:02:29
User entered '17/Feb/2021 11:35'	System	17 Feb 2021 16:35:19

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	25 Feb 2021 19:02:29
Reviewed for Safety.		17 Feb 2021 16:35:23
User entered '1'		17 Feb 2021 16:35:19

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:24:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 19:56:03
User entered '03/Mar/2021 09:01'	System	03 Mar 2021 14:01:52

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 19:56:03
Reviewed for Safety.		04 Mar 2021 20:19:39
User entered '1'		03 Mar 2021 14:01:52

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	(b) (4), (b) (6) 03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:24:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	13 Mar 2021 19:56:03
User entered '04/Mar/2021 14:20'	System	04 Mar 2021 20:20:25

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	13 Mar 2021 19:56:03
User entered 'I'		04 Mar 2021 20:20:25

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:27:16
User entered '0'		16 Mar 2021 16:48:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'USA-US061-2020-MRNA-1273-P301000014'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Yes (Y)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4)	03 Dec 2020 15:56:41
Reviewed for Safety.	(b) (4), (b) (6)	24 Nov 2020 13:03:10
User entered 'No (N)'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gregory'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Gottschlich'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '4260 Glendale Milford Road'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered 'Cincinnati'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		24 Nov 2020 13:03:10
User entered '45242'	System	24 Nov 2020 13:02:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	03 Dec 2020 15:56:41
Reviewed for Safety.		30 Nov 2020 15:05:46
User entered 'US'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form

Generated On: 09 Jun 2021 17:24:56

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '11'	System	16 Mar 2021 16:48:50
User entered '10'	System	04 Mar 2021 20:20:25
User entered '9'	System	03 Mar 2021 14:01:52
User entered '8'	System	17 Feb 2021 16:35:19
User entered '7'	System	07 Jan 2021 20:09:33
User entered '6'	System	04 Jan 2021 18:33:51
User entered '5'	System	23 Dec 2020 13:24:00
User entered '4'	System	07 Dec 2020 20:45:23
User entered '3'	System	02 Dec 2020 14:32:02
User entered '2'	System	30 Nov 2020 15:06:02
User entered '1'	System	24 Nov 2020 13:03:18

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 17:24:56

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	16 Mar 2021 18:27:16
User entered '16/Mar/2021 12:48'	System	16 Mar 2021 16:48:50

US3412013

Folder: SAE USA-US061-2020-MRNA-1273-P301000014

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 17:24:56

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	05 Apr 2021 14:58:01
DataPoint Verified.	(b) (4), (b) (6)	16 Mar 2021 18:27:16
User entered 'I'		16 Mar 2021 16:48:50