

US3412125 (Prod: New Horizons Clinical Research)

Generated By: KC Joubran

Generated On: 09 Jun 2021 17:32:44

All time stamps listed in this document are displayed in GMT

US3412125

Form: Participant Creation

Data signed: (b) (4) 16 Apr 2021 14:22:15

Generated On: 09 Jun 2021 17:32:44

Participant ID

US3412125

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

US3412125

Folder: Screening

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 04:49:36

Generated On: 09 Jun 2021 17:32:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	SCRN

US3412125

Folder: Screening

Form: Demographics

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

Date of Birth (MMM yyyy)	(b) (6) 1949
Age	71
Age Units	YEARS
Age (Derived)	71
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 04:49:09

Generated On: 09 Jun 2021 17:32:44

Date of Informed Consent (<i>dd MMM yyyy</i>)	04 AUG 2020
Month and Year of Informed Consent (derived)	AUG 2020
Year of Informed Consent (derived)	2020
Protocol Version	Amendment 1 <input checked="" type="radio"/>
	Amendment 2 <input type="radio"/>
	Amendment 3 <input type="radio"/>
	Amendment 4 <input type="radio"/>
	Amendment 5 <input type="radio"/>
Was participant enrolled in the study?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
If No, indicate reason for screen fail	Withdrew Consent <input type="radio"/>
	Inclusion/Exclusion <input type="radio"/>
	Cohort Full <input type="radio"/>
	Other <input type="radio"/>
If reason for screen fail is Other, specify	
Was this participant screened previously?	Yes <input type="radio"/>
	No <input checked="" type="radio"/>
If Yes, previous participant number	
Enrollment Trigger	1

US3412125

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

Did the participant meet all eligibility criteria?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History Summary

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

Were any significant conditions reported?

Yes ☒

No ☐

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Folder: Screening

Form: Medical History (1)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	HYPOTHYROID
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	
Stop Year (derived)	

US3412125

Folder: Screening

Form: Medical History (2)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: Screening

Form: Medical History (3)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	IBS-O
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412125

Folder: Screening

Form: Medical History (4)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	OSTEOARTHRITIS - BACK (LOW BACK)
Start date (dd MMM yyyy)	UN UNK 2014
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 2014
Start Year (derived)	2014
Stop Month and Year (derived)	
Stop Year (derived)	

US3412125

Folder: Screening

Form: Medical History (5)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	CHRONIC LOWER BACK PAIN
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412125

Folder: Screening

Form: Medical History (6)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	NON ACUTE SEROUS OTITIS MEDIA (NON-INFECTIOUS) "FLUID IN EAR" (BILATERAL)
Start date (dd MMM yyyy)	UN UNK 2000
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 2000
Start Year (derived)	2000
Stop Month and Year (derived)	
Stop Year (derived)	

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Folder: Screening

Form: Medical History (7)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	INTERMITTENT JOINT PAIN (ELBOWS / ANKLES, OCCASIONAL KNEES / HIPS)
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 (8)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

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

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Folder: Screening

Form: Medical History (9)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	GERD
Start date (dd MMM yyyy)	UN UNK 2009
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 2009
Start Year (derived)	2009
Stop Month and Year (derived)	_____
Stop Year (derived)	_____

US3412125

Folder: Screening

Form: Medical History (10)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

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

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Folder: Screening

Form: Medical History (11)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	RUPTURED DIVERTICULUM REPAIR
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (12)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	ILEOSTOMY
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Medical History (13)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

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

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Folder: Screening

Form: Medical History (14)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	TONSILLECTOMY
Start date (dd MMM yyyy)	UN UNK 1963
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1963
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1963
Start Year (derived)	1963
Stop Month and Year (derived)	JAN 1963
Stop Year (derived)	1963

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Folder: Screening

Form: Medical History (15)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	APPENDECTOMY
Start date (dd MMM yyyy)	UN UNK 1979
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 1979
Stop date completely unknown	False
Start Month and Year (derived)	JAN 1979
Start Year (derived)	1979
Stop Month and Year (derived)	JAN 1979
Stop Year (derived)	1979

US3412125

Folder: Screening

Form: Medical History (16)

Data signed: (b) (4) 16 Apr 2021 13:30:19

Generated On: 09 Jun 2021 17:32:44

Condition	BOWEL OBSTRUCTION
Start date (dd MMM yyyy)	UN UNK 2016
Start date completely unknown	False
Condition ongoing at study entry	Yes <input type="radio"/> No <input checked="" type="radio"/>
If No, please specify the stop date (dd MMM yyyy)	UN UNK 2016
Stop date completely unknown	False
Start Month and Year (derived)	JAN 2016
Start Year (derived)	2016
Stop Month and Year (derived)	JAN 2016
Stop Year (derived)	2016

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Folder: Screening

Form: Vital Signs

Data signed: (b) (4) 13 Feb 2021 04:49:36

Generated On: 09 Jun 2021 17:32:44

Were vital signs assessed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Date of assessment (<i>dd MMM yyyy</i>)	04 AUG 2020
Time of assessment (<i>00:00-23:59</i>)	14:35 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 14:35
Height (<i>xxx.x</i>)	158.0 cm
Weight (<i>xxx.x</i>)	54.7 kg
BMI (<i>xxx.x</i>)	21.91155 kg/m ²
BMI units	KG/M2
Temperature (<i>xxx.x</i>)	ND - Not Done
Route of measurement	Oral <input type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (<i>xxx</i>)	ND - Not Done
Pulse units	BPM
Respiratory Rate (<i>xxx</i>)	ND - Not Done
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (<i>xxx</i>)	ND - Not Done
Diastolic Blood Pressure units	MMHG
Height (derived)	
Weight (derived)	

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Folder: Screening

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 04:49:36

Generated On: 09 Jun 2021 17:32:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

04 AUG 2020

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

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Folder: Screening

Form: Childbearing Potential

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

Date of assessment (dd MMM yyyy) 04 AUG 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 2005

Date of last menstruation unknown False

US3412125

Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:49:36

Generated On: 09 Jun 2021 17:32:44

Occupational Risk

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

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

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

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

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

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

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

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

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

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

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

Other Yes ☐ No ☒

Specify

Location and Living Circumstances Risk (check all that apply)

No Risk Identified False

Resides in Nursing Home or Assisted Living Facility False

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Folder: Screening

Form: Risk of Exposure

Data signed: (b) (4) 13 Feb 2021 04:49:36

Generated On: 09 Jun 2021 17:32:44

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

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Folder: Visit 1 Day 1

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	04 AUG 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT1

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Folder: Visit 1 Day 1

Form: Randomization

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

What was the date of randomization? (dd MMM yyyy) 04 AUG 2020

What was the participant's randomization number? 184599

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

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

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

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

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

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

Liver Disease Yes ☐ No ☒

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Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

Height	ND - Not Done
Weight	ND - Not Done

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

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)	4 AUG 2020
Time of assessment (00:00-23:59)	14:35 (24 HR)
Vital Signs Date and Time (derived)	4 AUG 2020 14:35
Temperature (xxx.x)	36.7 C
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	70 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	124 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

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)	04 AUG 2020
Time of assessment (00:00-23:59)	16:26 (24 HR)
Vital Signs Date and Time (derived)	04 AUG 2020 16:26
Temperature (xxx.x)	97.4 F
Route of measurement	Oral <input checked="" type="radio"/> Axillary <input type="radio"/> Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	68 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	14 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	158 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	72 mmHg
Diastolic Blood Pressure units	MMHG

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Folder: Visit 1 Day 1

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

Was the physical examination performed?

Yes ☐

No ☒

Date of examination (dd MMM yyyy)

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

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Folder: Visit 1 Day 1

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:37:26

Generated On: 09 Jun 2021 17:32:44

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) 04 AUG 2020

What was the treatment time? (00:00-23:59) 15:55 (24 HR)

Treatment Date and Time (derived) 04 AUG 2020 15:55

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

What was the frequency of the study treatment dosing? ONCE

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

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Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	04 AUG 2020
Collection time (00:00-23:59)	15:28 (24 HR)
Collection date and time (derived)	04 AUG 2020 15:28

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Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:37:26

Generated On: 09 Jun 2021 17:32:44

Collection date (dd MMM yyyy)			04 AUG 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	15:34	04 AUG 2020 15:34
Nasopharyngeal Swab 2	No		

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Folder: Visit 1 Day 1

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:26

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

97.4 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 16:34

PC Open Date & Time

04 AUG 2020 16:15

PC Close Date & Time

04 AUG 2020 18:45

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

96.6 °F

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

Yes ☐

No ☒

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

PC Time Stamp

04 AUG 2020 20:09

PC Open Date & Time

04 AUG 2020 19:40

PC Close Date & Time

05 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

95.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

05 AUG 2020 19:39

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 3

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.5 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 AUG 2020 19:45

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

97.6 °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

07 AUG 2020 19:40

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 5

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

97.3 °F

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

Yes ☐

No ☒

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

PC Time Stamp

08 AUG 2020 19:20

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 6

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.1 °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

09 AUG 2020 19:06

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.3 °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

10 AUG 2020 19:01

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

04 AUG 2020 16:37

PC Open Date & Time

04 AUG 2020 16:15

PC Close Date & Time

04 AUG 2020 18:45

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

04 AUG 2020 20:09

PC Open Date & Time

04 AUG 2020 19:40

PC Close Date & Time

05 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

05 AUG 2020 19:39

PC Open Date & Time

05 AUG 2020 12:00

PC Close Date & Time

06 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

06 AUG 2020 19:45

PC Open Date & Time

06 AUG 2020 12:00

PC Close Date & Time

07 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

07 AUG 2020 19:41

PC Open Date & Time

07 AUG 2020 12:00

PC Close Date & Time

08 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

08 AUG 2020 19:20

PC Open Date & Time

08 AUG 2020 12:00

PC Close Date & Time

09 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 6

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

09 AUG 2020 19:07

PC Open Date & Time

09 AUG 2020 12:00

PC Close Date & Time

10 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

10 AUG 2020 19:02

PC Open Date & Time

10 AUG 2020 12:00

PC Close Date & Time

11 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 16:38
PC Open Date & Time	04 AUG 2020 16:15
PC Close Date & Time	04 AUG 2020 18:45

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

No ☒

Yes ☐

PC Time stamp	04 AUG 2020 20:10
PC Open Date & Time	04 AUG 2020 19:40
PC Close Date & Time	05 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 2

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	05 AUG 2020 19:40
PC Open Date & Time	05 AUG 2020 12:00
PC Close Date & Time	06 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

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 ☒

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	06 AUG 2020 19:46
PC Open Date & Time	06 AUG 2020 12:00
PC Close Date & Time	07 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

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 ☒

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	07 AUG 2020 19:41
PC Open Date & Time	07 AUG 2020 12:00
PC Close Date & Time	08 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

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 ☒

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	08 AUG 2020 19:21
PC Open Date & Time	08 AUG 2020 12:00
PC Close Date & Time	09 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 6

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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EAB) (1725)

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	09 AUG 2020 19:07
PC Open Date & Time	09 AUG 2020 12:00
PC Close Date & Time	10 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

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 ☒

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	10 AUG 2020 19:03
PC Open Date & Time	10 AUG 2020 12:00
PC Close Date & Time	11 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your

None ☒

HEADACHE

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp 11 AUG 2020 19:05

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **MUSCLE**

ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 11 AUG 2020 19:05

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **MUSCLE**

None ☒

ACHES ALL OVER BODY

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp 12 AUG 2020 19:11

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp	11 AUG 2020 19:05
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PC Open Date & Time	11 AUG 2020 12:00
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PC Close Date & Time	12 AUG 2020 11:59
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US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp 12 AUG 2020 19:12

PC Open Date & Time 12 AUG 2020 12:00

PC Close Date & Time 13 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 8

Select one response below to indicate the level of your

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 ☐

PC Time stamp 11 AUG 2020 19:05

PC Open Date & Time 11 AUG 2020 12:00

PC Close Date & Time 12 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	11 AUG 2020 19:05
PC Open Date & Time	11 AUG 2020 12:00
PC Close Date & Time	12 AUG 2020 11:59

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input checked="" type="radio"/> Yes <input type="radio"/>
PC Time stamp	12 AUG 2020 19:12
PC Open Date & Time	12 AUG 2020 12:00
PC Close Date & Time	13 AUG 2020 11:59

US3412125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: Safety Call Day 8 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: Safety Call Day 15 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

Was Contact Attempted?

Yes ☒

No ☐

Date of Contact or Contact Attempt (dd MMM yyyy)

25 AUG 2020

Please select one status for the follow-up contact

Contact Made ☒

Contact Not Made ☐

Comments

If Contact Not Made, please provide Comments

US3412125

Folder: Safety Call Day 22 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

Was this visit performed?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Visit date (dd MMM yyyy)	01 SEP 2020
Was visit performed at the participant's home or at the clinic?	Home <input type="radio"/>
	Clinic <input checked="" type="radio"/>
Folder OID	VISIT2

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

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)	01 SEP 2020
Time of assessment (00:00-23:59)	12:00 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 12:00
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)	60 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	16 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	110 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	64 mmHg
Diastolic Blood Pressure units	MMHG

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

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)	01 SEP 2020
Time of assessment (00:00-23:59)	13:25 (24 HR)
Vital Signs Date and Time (derived)	01 SEP 2020 13:25
Temperature (xxx.x)	97.1 F
Route of measurement	Oral <input checked="" type="radio"/>
	Axillary <input type="radio"/>
	Other <input type="radio"/>
If Other, specify	
Pulse (xxx)	62 beats/min
Pulse units	BPM
Respiratory Rate (xxx)	12 breaths/min
Respiratory Rate units	BREATHS/MIN
Systolic Blood Pressure (xxx)	130 mmHg
Systolic Blood Pressure units	MMHG
Diastolic Blood Pressure (xxx)	68 mmHg
Diastolic Blood Pressure units	MMHG

US3412125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

Was the physical examination performed?

Yes ☒

No ☐

Date of examination (dd MMM yyyy)

01 SEP 2020

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

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

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) 01 SEP 2020

What was the treatment time? (00:00-23:59) 12:55 (24 HR)

Treatment Date and Time (derived) 01 SEP 2020 12:55

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

What was the frequency of the study treatment dosing? ONCE

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

US3412125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

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

Collection date (dd MMM yyyy)	01 SEP 2020
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Collection time (00:00-23:59)	12:08 (24 HR)
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Collection date and time (derived)	01 SEP 2020 12:08
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US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

Collection date (dd MMM yyyy)			01 SEP 2020
Lab Test	Was the sample collected?	Collection time (00:00 - 23:59)	Collection date and time (derived)
Nasopharyngeal Swab 1	Yes	12:12	01 SEP 2020 12:12
Nasopharyngeal Swab 2	No		

US3412125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 02:37:27

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

97.1 °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

01 SEP 2020 13:30

PC Open Date & Time

01 SEP 2020 13:15

PC Close Date & Time

01 SEP 2020 15:45

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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 97.3 °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	01 SEP 2020 19:06
PC Open Date & Time	01 SEP 2020 16:40
PC Close Date & Time	02 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

97.1 °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

02 SEP 2020 19:53

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

96.8 °F

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

Yes ☐

No ☒

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

PC Time Stamp

03 SEP 2020 20:44

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

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 97.3 °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):

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

To **PREVENT** pain or fever from occurring False

PC Time Stamp 04 SEP 2020 19:04

PC Open Date & Time 04 SEP 2020 12:00

PC Close Date & Time 05 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

95.7 °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 SEP 2020 19:42

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

97.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

06 SEP 2020 19:56

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 7

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

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

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

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

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

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

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

Was **TEMPERATURE** taken?

Yes ☒

No ☐

Please record your **TEMPERATURE** in °F

98.0 °F

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

Yes ☐

No ☒

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

PC Time Stamp

07 SEP 2020 19:36

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

01 SEP 2020 13:30

PC Open Date & Time

01 SEP 2020 13:15

PC Close Date & Time

01 SEP 2020 15:45

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

01 SEP 2020 19:07

PC Open Date & Time

01 SEP 2020 16:40

PC Close Date & Time

02 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

02 SEP 2020 19:54

PC Open Date & Time

02 SEP 2020 12:00

PC Close Date & Time

03 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

03 SEP 2020 20:44

PC Open Date & Time

03 SEP 2020 12:00

PC Close Date & Time

04 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 4

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

None ☐

Please select one response below

Does not interfere with activity ☒

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

Any use of prescription pain
reliever or prevents daily activity ☐

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

Yes ☐

No ☒

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

Yes ☐

No ☒

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

None ☒

Please select one response below

Does not interfere with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

PC Time Stamp

04 SEP 2020 19:05

PC Open Date & Time

04 SEP 2020 12:00

PC Close Date & Time

05 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

05 SEP 2020 19:43

PC Open Date & Time

05 SEP 2020 12:00

PC Close Date & Time

06 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

06 SEP 2020 19:57

PC Open Date & Time

06 SEP 2020 12:00

PC Close Date & Time

07 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

07 SEP 2020 19:38

PC Open Date & Time

07 SEP 2020 12:00

PC Close Date & Time

08 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 13:31
PC Open Date & Time	01 SEP 2020 13:15
PC Close Date & Time	01 SEP 2020 15:45

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

No ☒

Yes ☐

PC Time stamp	01 SEP 2020 19:07
PC Open Date & Time	01 SEP 2020 16:40
PC Close Date & Time	02 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

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 ☒

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	02 SEP 2020 19:56
PC Open Date & Time	02 SEP 2020 12:00
PC Close Date & Time	03 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 3

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

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Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	03 SEP 2020 20:45
PC Open Date & Time	03 SEP 2020 12:00
PC Close Date & Time	04 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

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 ☒

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	04 SEP 2020 19:07
PC Open Date & Time	04 SEP 2020 12:00
PC Close Date & Time	05 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

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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US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	05 SEP 2020 19:44
PC Open Date & Time	05 SEP 2020 12:00
PC Close Date & Time	06 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

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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US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	06 SEP 2020 19:57
PC Open Date & Time	06 SEP 2020 12:00
PC Close Date & Time	07 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 7

HEADACHE

None ☒

No interference with activity ☐

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

Any use of prescription pain
reliever or prevents daily activity ☐

FATIGUE

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

MUSCLE ACHES ALL OVER BODY

None ☒

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

JOINT ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☒

Some interference with activity ☐

Significant; prevents daily
activity ☐

NAUSEA/VOMITING

None ☒

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

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

Prevents daily activity, requires
outpatient IV hydration ☐

CHILLS

None ☒

No interference with activity ☐

Some interference with activity
not requiring medical attention ☐

Prevents daily activity and
requires medical attention ☐

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

No ☒

PRODUCTION RELEASE (v12.003

EAB) (1725)

122 of 4013

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

Yes <input type="checkbox"/>	
PC Time stamp	07 SEP 2020 19:39
PC Open Date & Time	07 SEP 2020 12:00
PC Close Date & Time	08 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 8

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 ☐

PC Time Stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 9

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 ☐

PC Time Stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 8

Select one response below to indicate the intensity of your **JOINT**
ACHES IN SEVERAL JOINTS

None ☐

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily
activity ☐

PC Time stamp

PC Open Date & Time

08 SEP 2020 12:00

PC Close Date & Time

09 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 9

Select one response below to indicate the intensity of your **JOINT**

None ☐

ACHES IN SEVERAL JOINTS

No interference with activity ☐

Some interference with activity ☐

Significant; prevents daily activity ☐

PC Time stamp

PC Open Date & Time

09 SEP 2020 12:00

PC Close Date & Time

10 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 8
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	08 SEP 2020 12:00
PC Close Date & Time	09 SEP 2020 11:59

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 9
Did you receive any MEDICAL ATTENTION (doctor visit, other) for any illness or symptoms?	No <input type="checkbox"/>
	Yes <input type="checkbox"/>
PC Time stamp	
PC Open Date & Time	09 SEP 2020 12:00
PC Close Date & Time	10 SEP 2020 11:59

US3412125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 08 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

US3412125

Folder: Safety Call Day 36 (1)

Form: Continuing

Data signed: (b) (4) 13 Feb 2021 04:49:09

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:18

Generated On: 09 Jun 2021 17:32:44

Was Contact Attempted? Yes ☒
No ☐

Date of Contact or Contact Attempt (dd MMM yyyy) 15 SEP 2020

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

Comments

If Contact Not Made, please provide Comments

SUBJECT WAS IN A SERIOUS
MOTOR VEHICLE ACCIDENT
ON 08AUG2020 AND WAS
HOSPITALIZED. SITE REACHED
OUT TO SUBJECT AS WELL AS
SUBJECT'S SPOUSE BUT WAS
NOT ABLE TO MAKE CONTACT.

US3412125

Folder: Safety Call Day 43 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:18

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:32:44

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

SUBJECT WAS IN A MOTOR
VEHICLE ACCIDENT ON
08AUG2020. SINCE NOTIFYING
THE SITE THE DATE AFTER,
SUBJECT HAS NOT BEEN
REACHABLE AND HAS NOT
REACHED OUT.

US3412125

Folder: Safety Call Day 50 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:19

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:32:44

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID VISIT3

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:32:44

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) _____

US3412125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:32:44

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.

US3412125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:32:44

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3412125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 checked="" type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input checked="" type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input checked="" type="radio"/>
Date and time of submission	07 OCT 2020 18:02:36
Patient Cloud Open Date & Time	04 OCT 2020 00:01
Patient Cloud Close Date & Time	08 OCT 2020 23:59

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

11 OCT 2020 00:01

Patient Cloud Close Date & Time

15 OCT 2020 23:59

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

Patient Cloud Close Date & Time

22 OCT 2020 23:59

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 92
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature \geq 100.4°F/38°C)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

Patient Cloud Close Date & Time

05 NOV 2020 23:59

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

Patient Cloud Close Date & Time

12 NOV 2020 23:59

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 106
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="checkbox"/> Yes <input type="checkbox"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<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"/>

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

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

Date and time of submission

Patient Cloud Open Date & Time

15 NOV 2020 00:01

Patient Cloud Close Date & Time

19 NOV 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 110
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

19 NOV 2020 00:01

[Patient Cloud Close Date & Time](#)

23 NOV 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

30 NOV 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 124
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Open Date & Time](#)

03 DEC 2020 00:01

[Patient Cloud Close Date & Time](#)

07 DEC 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 131
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	14 DEC 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2020 00:01
Patient Cloud Close Date & Time	21 DEC 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 <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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

28 DEC 2020 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 <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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

04 JAN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 159

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

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Open Date & Time](#)

07 JAN 2021 00:01

[Patient Cloud Close Date & Time](#)

11 JAN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

18 JAN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

01 FEB 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 187
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input 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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	08 FEB 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 201
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	18 FEB 2021 00:01
Patient Cloud Close Date & Time	22 FEB 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 <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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

01 MAR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 <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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

08 MAR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

15 MAR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 236
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input 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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

29 MAR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Open Date & Time](#)

01 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

05 APR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Open Date & Time](#)

08 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

12 APR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

19 APR 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 <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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

Patient Cloud Open Date & Time	22 APR 2021 00:01
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Patient Cloud Close Date & Time	26 APR 2021 23:59
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US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 <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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Open Date & Time](#)

29 APR 2021 00:01

[Patient Cloud Close Date & Time](#)

03 MAY 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 278

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

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

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

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

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

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

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

10 MAY 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 285
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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	13 MAY 2021 00:01
Patient Cloud Close Date & Time	17 MAY 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

24 MAY 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

31 MAY 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	07 JUN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 313

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

14 JUN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

21 JUN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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="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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Open Date & Time](#)

24 JUN 2021 00:01

[Patient Cloud Close Date & Time](#)

28 JUN 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 334
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

05 JUL 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
Patient Cloud Close Date & Time	12 JUL 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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="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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 362
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

02 AUG 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

09 AUG 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 <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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 2021 00:01
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Patient Cloud Close Date & Time	16 AUG 2021 23:59
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US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

23 AUG 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Open Date & Time](#)

26 AUG 2021 00:01

[Patient Cloud Close Date & Time](#)

30 AUG 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

06 SEP 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

13 SEP 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

20 SEP 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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°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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

30 SEP 2021 00:01

[Patient Cloud Close Date & Time](#)

04 OCT 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 <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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Open Date & Time](#)

07 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

11 OCT 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Open Date & Time](#)

21 OCT 2021 00:01

[Patient Cloud Close Date & Time](#)

25 OCT 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 453

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

01 NOV 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

08 NOV 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 467
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

22 NOV 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 481

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

29 NOV 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	06 DEC 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

13 DEC 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	20 DEC 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 509

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 DEC 2021 00:01
Patient Cloud Close Date & Time	27 DEC 2021 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

03 JAN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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°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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

10 JAN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 530
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

17 JAN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

24 JAN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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°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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 JAN 2022 00:01
Patient Cloud Close Date & Time	31 JAN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

07 FEB 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

14 FEB 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 565

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 572

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

28 FEB 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

07 MAR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

14 MAR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

21 MAR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

28 MAR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 607

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

04 APR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 APR 2022 00:01
Patient Cloud Close Date & Time	11 APR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

18 APR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 APR 2022 00:01
Patient Cloud Close Date & Time	25 APR 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

02 MAY 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 642
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

09 MAY 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 649
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

16 MAY 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

23 MAY 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

30 MAY 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

06 JUN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

13 JUN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

20 JUN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

27 JUN 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

04 JUL 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

11 JUL 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 <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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

18 JUL 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 719
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="checkbox"/>
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Date and time of submission	
Patient Cloud Open Date & Time	21 JUL 2022 00:01
Patient Cloud Close Date & Time	25 JUL 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

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

Date and time of submission

[Patient Cloud Open Date & Time](#)

28 JUL 2022 00:01

[Patient Cloud Close Date & Time](#)

01 AUG 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 733

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

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

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

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

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

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

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

08 AUG 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 AUG 2022 00:01
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Patient Cloud Close Date & Time	15 AUG 2022 23:59
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US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT	DAY 747
Have you had any changes in your health since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Have you been exposed to someone with known SARS-CoV-2 infection or COVID-19 disease since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you experienced any new COVID-19 disease symptoms since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>
Please identify below which symptoms you have experienced or are experiencing (Check all that apply):	
Fever (Temperature $\geq 100.4^{\circ}\text{F}/38^{\circ}\text{C}$)	<input type="checkbox"/>
Chills	<input type="checkbox"/>
Cough	<input type="checkbox"/>
Shortness of breath	<input type="checkbox"/>
Difficulty breathing	<input type="checkbox"/>
Fatigue	<input type="checkbox"/>
Muscle aches	<input type="checkbox"/>
Body aches	<input type="checkbox"/>
Headache	<input type="checkbox"/>
New loss of taste	<input type="checkbox"/>
New loss of smell	<input type="checkbox"/>
Sore throat	<input type="checkbox"/>
Congestion	<input type="checkbox"/>
Runny nose	<input type="checkbox"/>
Nausea	<input type="checkbox"/>
Vomiting	<input type="checkbox"/>
Diarrhea	<input type="checkbox"/>
Please contact your study clinic immediately. Click below to confirm that you have read this message and understood that you must call your study clinic.	I confirm I have read this message and will call the study clinic immediately <input type="radio"/>
Have you had to contact a healthcare provider since the last time you completed this questionnaire or had contact with the study clinic?	No <input type="radio"/> Yes <input type="radio"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

22 AUG 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 754

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

29 AUG 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

05 SEP 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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"/>

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	12 SEP 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Please contact your study clinic immediately. Click below to confirm that you have read this message and understood 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 SEP 2022 00:01
Patient Cloud Close Date & Time	19 SEP 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 782

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

26 SEP 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

DAY 789

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

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

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

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

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

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

Chills ☐

Cough ☐

Shortness of breath ☐

Difficulty breathing ☐

Fatigue ☐

Muscle aches ☐

Body aches ☐

Headache ☐

New loss of taste ☐

New loss of smell ☐

Sore throat ☐

Congestion ☐

Runny nose ☐

Nausea ☐

Vomiting ☐

Diarrhea ☐

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

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

[Patient Cloud Close Date & Time](#)

03 OCT 2022 23:59

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

Date and time of submission	
Patient Cloud Open Date & Time	06 OCT 2022 00:01
Patient Cloud Close Date & Time	10 OCT 2022 23:59

US3412125

Folder: Cosmetic Injections and Dermal Fillers

Form: Cosmetic Injection_ Dermal Filler eDiary

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:32:44

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

SITE REACHED OUT TO
SUBJECT AND LEFT MULTIPLE
VOICEMAILS AFTER
RECEIVING A SAFETY FOLLOW
UP ALERT ON 07OCT2020. SITE
DID NOT ATTEMPT THIS CALL
AS SUBJECT HAD NOT
RESPONDED TO ANY PREVIOUS
ATTEMPTS.

US3412125

Folder: Safety Call Day 85 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:25

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:18

Generated On: 09 Jun 2021 17:32:44

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

SITE DID NOT ATTEMPT
CONTACT AS SUBJECT HAD
BEEN UNRESPONSIVE SINCE
THEIR MOTOR VEHICLE
ACCIDENT ON 08AUG2020.

US3412125

Folder: Safety Call Day 119 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:18

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:18

Generated On: 09 Jun 2021 17:32:44

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

SITE DID NOT ATTEMPT
CONTACT AS SUBJECT HAD
BEEN UNRESPONSIVE SINCE
THEIR MOTOR VEHICLE
ACCIDENT ON 08AUG2020.

US3412125

Folder: Safety Call Day 149 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:18

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Data signed: (b) (4) 16 Apr 2021 14:22:18

Generated On: 09 Jun 2021 17:32:44

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

SITE INADVERTENTLY DID NOT
RESUME SAFETY CALLS AFTER
SHE CAME INTO SITE FOR
UNBLINDING ON 22JAN2021.

US3412125

Folder: Safety Call Day 179 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:18

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☒

No ☐

Continuing Flag

1

US3412125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:32:44

Was this visit performed? Yes ☐
No ☒

Visit date (dd MMM yyyy)

Was visit performed at the participant's home or at the clinic? Home ☐
Clinic ☐

Folder OID VISIT4

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:32:44

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) _____

US3412125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:32:44

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.

US3412125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:32:44

Was the sample collected?

Yes ☐

No ☒

Collection date (dd MMM yyyy)

Collection time (00:00-23:59)

Collection date and time (derived)

US3412125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Data signed: (b) (4) 16 Apr 2021 14:22:26

Generated On: 09 Jun 2021 17:32:44

Is the participant continuing to the next visit?

Yes ☐

No ☒

Continuing Flag

US3412125

Folder: Covid-19 Assessment (1)

Form: COVID-19 Contact

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: Covid-19 Assessment (1)

Form: Generate Next COVID-19 Assessment

Generated On: 09 Jun 2021 17:32:44

Generate Next COVID-19 Assessment

Yes ☐

No ☐

US3412125

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

Form: Visit Date

Data signed: (b) (4) 16 Apr 2021 14:22:15

Generated On: 09 Jun 2021 17:32:44

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

Visit date (dd MMM yyyy)	22 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
------------	---------------

US3412125

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

Form: Unblinding

Data signed: (b) (4) 16 Apr 2021 14:22:15

Generated On: 09 Jun 2021 17:32:44

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) 22 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 _____

US3412125

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

Form: Immunogenicity Assessment

Data signed: (b) (4) 16 Apr 2021 14:22:15

Generated On: 09 Jun 2021 17:32:44

Was the sample collected?

Yes ☒

No ☐

Collection date (dd MMM yyyy)

22 JAN 2021

Collection time (00:00-23:59)

14:00 (24 HR)

Collection date and time (derived)

22 JAN 2021 14:00

US3412125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Data signed: (b) (4) 16 Apr 2021 14:22:15

Generated On: 09 Jun 2021 17:32:44

Was the sample collected?	Yes <input checked="" type="radio"/>
	No <input type="radio"/>
Collection date (dd MMM yyyy)	22 JAN 2021
Collection time (00:00 - 23:59)	14:02
Collection Date and Time (derived)	22 JAN 2021 14:02

US3412125

Folder: Adverse Events

Form: Adverse Events Summary

Data signed: (b) (4) 15 Mar 2021 15:30:59

Generated On: 09 Jun 2021 17:32:44

Did the participant experience any adverse events?

Yes ☒

No ☐

If Yes, enter details on the Adverse Events form.

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	MOTOR VEHICLE ACCIDENT
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)	08 SEP 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)	08 SEP 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	True
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	10

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

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 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	

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

71 YOF HISTORY OF OPEN
SUBTOTAL COLECTOMY WITH
END ILEOSTOMY S/P
REVERSAL WITH LOWER
MIDLINE INCISIONAL HERNIA
S/P LAPAROSCOPIC REPAIR
WITH MESH WHO PRESENTS S/P
MVC ON SEP 8,2020 WITH
MULTIPLE INJURIES
INCLUDING SUBARACHNOID
HEMORRHAGE, BLUNT
CEREBROVASCULAR INJURY
WITH SUBSEQUENT STROKE
AND SEIZURE, GRADE IV LIVER
LACERATION, AND RIGHT
TIBIAL AND FIBULAR
FRACTURES. GIVEN HER
ANTICIPATED PROLONGED
NEED FOR VENTILATORY
SUPPORT AND ENTERAL
NUTRITION A TRACHEOSTOMY
AND PEG WERE PERFORMED.
OF NOTE, THE PATIENT ALSO
HAS AN EXTENSIVE
ABDOMINAL SURGICAL
HISTORY INCLUDING
SUBTOTAL COLECTOMY WITH
ILEORECTAL ANASTOMOSIS
AND SUBSEQUENT VENTRAL
HERNIA REPAIR WITH
PERMANENT MESH.

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)	1

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	TRAUMATIC BRAIN INJURY
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)	23 SEP 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)	01 OCT 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)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	10

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

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 checked="" type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	FUNCTION OF SUBJECT CONFUSION, WEAKNESS
Narrative	SUBJECT WAS IN MOTOR VEHICLE ACCIDENT
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)	1

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	MULTIPLE LEFT HEMISPHERE EMBOLIC INFARCT
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)	09 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	10
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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input checked="" type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WAS IN MOTOR VEHICLE ACCIDENT
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)	1

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	LEFT INTERCAROTID ARTERY DISSECTION WITH INTRALUMINAL THROMBUS
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)	13 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

Number of Days in ICU	10
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 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	MOTOR VEHICLE ACCIDENT
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)	1

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	CERVICAL 7 FRACTURE
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)	09 SEP 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)	09 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)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	10

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

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 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	SUBJECT WAS IN MOTOR VEHICLE ACCIDENT
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)	1

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

AEID

Adverse event

NONDISPLACED RIB
FRACTURES RIGHT 1-2

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)

09 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)

19 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 ☐

Number of Days in ICU

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

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 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)	1

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	MRSA PNEUMONIA
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)	09 SEP 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)	29 SEP 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)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	10

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Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

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	SUBJECT WAS IN MOTOR VEHICLE ACCIDENT
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)	1

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	NON STEMI
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)	13 SEP 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)	13 SEP 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)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	10

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Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

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 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	SUBJECT WAS IN MOTOR VEHICLE ACCIDENT
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)	1

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	GRADE IV LIVER LACERATION
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)	09 SEP 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)	28 JAN 2021
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	10

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input 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	SUBJECT WAS IN MOTOR VEHICLE ACCIDENT
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)	1

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	ACUTE POST HEMORRHAGIC ANEMIA
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)	08 SEP 2020
Start time (00:00-23:59)	
AE start date and time (derived)	
Ongoing?	Yes <input checked="" type="radio"/> No <input type="radio"/>
If not Ongoing, end date (dd MMM yyyy)	
End time (00:00-23:59)	
AE End Date and Time (derived)	
Severity	Grade 1/Mild <input type="radio"/> Grade 2/Moderate <input type="radio"/> Grade 3/Severe <input type="radio"/> Grade 4 <input checked="" type="radio"/>
Is the adverse event serious?	Yes <input checked="" type="radio"/> No <input type="radio"/>
AE is serious due To (check all that apply)	
Death	False
Life threatening	False
Requires inpatient or prolongation of existing Hospitalization	True
Hospital Admission Date (dd MMM yyyy)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	10
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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

Persistent or significant disability or incapacity	False
Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input type="radio"/> Dose Delayed <input type="radio"/> Investigational Product <input type="radio"/> Withdrawn <input type="radio"/> Not Applicable <input checked="" type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	False
Concomitant Procedure	True
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input checked="" type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT WAS INVOLVED IN MOTOR VEHICLE ACCIDENT
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)	1

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

AEID

Adverse event

RIGHT TIB/ FIB FRACTURE

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)

13 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)

24 FEB 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

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

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	False
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 _____	
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 (12)

Generated On: 09 Jun 2021 17:32:44

AEID

Adverse event

HYPERGLYCEMIA

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)

13 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)

09 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 ☐

Number of Days in ICU

Persistent or significant disability or incapacity False

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Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

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)	1
Admitted to ICU Derived (CSA Programming Field Only) _____	

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

AEID

Adverse event

HYPONATREMIA

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)

13 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)

09 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 ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

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)	1
Admitted to ICU Derived (CSA Programming Field Only)	_____

US3412125

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:32:44

AEID	USA-US061-2020-MRNA-1273-P30 1000005
Adverse event	SUBARACHNOID HEMORRAGE
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)	23 SEP 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)	01 OCT 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)	08 SEP 2020
Hospital Discharge Date (dd MMM yyyy)	01 OCT 2020
Admitted to ICU?	Yes <input checked="" type="radio"/> No <input type="radio"/> Unknown <input type="radio"/>
Number of Days in ICU	10
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Folder: Adverse Events

Form: Adverse Events (14)

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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	False
Concomitant Medication	False
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	

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Folder: Adverse Events

Form: Adverse Events (14)

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71 YOF HISTORY OF OPEN
SUBTOTAL COLECTOMY WITH
END ILEOSTOMY S/P
REVERSAL WITH LOWER
MIDLINE INCISIONAL HERNIA
S/P LAPAROSCOPIC REPAIR
WITH MESH WHO PRESENTS S/P
MVC ON SEP 8,2020 WITH
MULTIPLE INJURIES
INCLUDING SUBARACHNOID
HEMORRHAGE, BLUNT
CEREBROVASCULAR INJURY
WITH SUBSEQUENT STROKE
AND SEIZURE, GRADE IV LIVER
LACERATION, AND RIGHT
TIBIAL AND FIBULAR
FRACTURES. GIVEN HER
ANTICIPATED PROLONGED
NEED FOR VENTILATORY
SUPPORT AND ENTERAL
NUTRITION A TRACHEOSTOMY
AND PEG WERE PERFORMED.
OF NOTE, THE PATIENT ALSO
HAS AN EXTENSIVE
ABDOMINAL SURGICAL
HISTORY INCLUDING
SUBTOTAL COLECTOMY WITH
ILEORECTAL ANASTOMOSIS
AND SUBSEQUENT VENTRAL
HERNIA REPAIR WITH
PERMANENT MESH.

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)	1

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

AEID

Adverse event

SEIZURE

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)

08 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)

08 SEP 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 ☐

Number of Days in ICU

Persistent or significant disability or incapacity

False

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Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

Congenital anomaly or birth defect	False
Other medically important event	False
Relationship to investigational product	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Relationship to Study Procedure	Not Related <input checked="" type="radio"/> Related <input type="radio"/> Not Applicable <input type="radio"/>
Action taken with investigational product	None <input checked="" type="radio"/> Dose Delayed <input type="radio"/> Investigational Product Withdrawn <input type="radio"/> Not Applicable <input type="radio"/>
Other action taken (check all that apply)	
None	False
Concomitant Medication	True
Concomitant Procedure	False
Outcome	Fatal <input type="radio"/> Not Recovered/Not Resolved <input type="radio"/> Recovered/Resolved <input checked="" type="radio"/> Recovered/Resolved with Sequelae <input type="radio"/> Recovering/Resolving <input type="radio"/> Unknown <input type="radio"/>
If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:	
Narrative	SUBJECT EXPERIENCE GENERALIZED TONIC CLINIC SEIZURE ACTIVITY WHICH WAS RESOLVED WITH LORAZEPAM AND KEPPRA
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: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Data signed: (b) (4) 12 Apr 2021 14:34:56

Generated On: 09 Jun 2021 17:32:44

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

Yes ☒

No ☐

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

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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EAB) (1725)

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	19 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"/>

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication ATENOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 35

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)

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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"/>

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication CYCLOBENZAPRINE

Prophylaxis Yes ☐
No ☒

Indication CHRONIC LOW BACK PAIN

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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 2009	
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"/>

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication DICYCLOMINE
HYDROCHLORIDE

Prophylaxis Yes ☐
No ☒

Indication IRRITABLE BOWEL
SYNDROME-D

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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 2000	
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 (5)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROID

Dose per administration 75

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)	03 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication LOSARTAN

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (6)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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"/>

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication MELOXICAM

Prophylaxis Yes ☐
No ☒

Indication OSTEOARTHRITIS

Dose per administration 15

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) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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 (8)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication PSEUOBEPHEDRINE

Prophylaxis Yes ☐
No ☒

Indication SEROUS OTITIS MEDIA

Dose per administration 120

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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 2000
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"/>

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication VITAMIN D

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

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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US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication CALCIUM

Prophylaxis Yes ☐
No ☒

Indication GENERAL HEALTH

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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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication OA

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN UNK 2019	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 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 (12)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication METAMUCIAL

Prophylaxis Yes ☐
No ☒

Indication IBS

Dose per administration 1

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

If dose unit is Other, specify EIGHT OUNCE GLASS WITH SACHET

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 (12)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication AMANTADINE HCL

Prophylaxis Yes ☒
No ☐

Indication TRAUMATIC BRAIN INJURY

Dose per administration 50

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	PER GASTRIC TUBE	
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication APIRABAN

Prophylaxis Yes ☐
No ☒

Indication LEFT INTERCAROTID ARTERY
DISSECTION WITH
INTRALUMINAL THROMBUS

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)		01 OCT 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 (16)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication CARVEDIOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 3.125

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)		01 OCT 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 (17)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication ESOMEPRAZOLE

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 (17)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	PER GASTRIC TUBE	
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication FERROUS SULFATE

Prophylaxis Yes ☐
No ☒

Indication ANEMIA

Dose per administration 325

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)		08 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"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication INSULIN GLARGINE

Prophylaxis Yes ☐
No ☒

Indication HYPERGLYCEMIA

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 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 (20)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication INSULIN REGULAR

Prophylaxis Yes ☐
No ☒

Indication HYPERGLYCEMIA

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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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) 09 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"/>

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HYPONATREMIA

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 (21)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	PER NASOGASTRIC TUBE	
Start date (dd MMM yyyy)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)	3	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication PANTAPROZOLE

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 (22)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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 2009	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)	01 OCT 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 (23)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication VANCOMYCIN

Prophylaxis Yes ☐
No ☒

Indication MRSA PNEUMONIA

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		UNKNOWN
Start date (dd MMM yyyy)		09 SEP 2020
Start date completely unknown		False
Ongoing?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)		29 SEP 2020
Was this medication taken for solicited event?		Yes <input type="radio"/>
		No <input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)		802 <input type="radio"/>
		803 <input type="radio"/>
		804 <input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication CEFEPIME

Prophylaxis Yes ☐
No ☒

Indication MRSA PNEUMONIA

Dose per administration UNK

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

If dose unit is Other, specify UNKNOWN

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	UNKNOWN	
Start date (dd MMM yyyy)	09 SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
If not Ongoing, End date (dd MMM yyyy)	29 SEP 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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 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)	01 OCT 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		01 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 (26)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication KEPPRA

Prophylaxis Yes ☒
No ☐

Indication SEIZURE PREVENTION

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)		08 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)		15 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) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication LORAZEPAM

Prophylaxis Yes ☐
No ☒

Indication SEIZURE

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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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 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)		08 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)		08 SEP 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) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication MODAFINIL

Prophylaxis Yes ☐
No ☒

Indication PROMOTE WAKEFULNESS

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)		08 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)		01 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 (29)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication METROPOLOL

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration UNK

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

If dose unit is Other, specify UNK

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	UN SEP 2020	
Start date completely unknown	False	
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) UN 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 (30)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication INJECTION SITE PAIN

Dose per administration 500

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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 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)		04 SEP 2020
Was this medication taken for solicited event?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication ELIQUIS

Prophylaxis Yes ☒
No ☐

Indication THROMBOEMBOLISM
PREVENTION

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)		02 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) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication CLONAZEPAM

Prophylaxis Yes ☐
No ☒

Indication SEIZURES

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 (32)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication AMLODIPINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

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 (33)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)	20 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)	01 JAN 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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Name of Medication VOLTAREN

Prophylaxis Yes ☐
No ☒

Indication MOTOR VEHICLE ACCIDENT

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)		13 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"/>

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication VITAMIN D2

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 50000

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication GABAPENTIN

Prophylaxis Yes ☐
No ☒

Indication MOTOR VEHICLE ACCIDENT

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 (36)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication APRESOLINE

Prophylaxis Yes ☐
No ☒

Indication HYPERTENSION

Dose per administration 5

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)	02 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)	01 FEB 2021	
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 (38)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication LEVOTHYROXINE

Prophylaxis Yes ☐
No ☒

Indication HYPOTHYROIDISM

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 (38)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication LIDOCAINE 4%

Prophylaxis Yes ☐
No ☒

Indication PAIN DUE TO MOTOR VEHICLE
ACCIDENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)	14 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)	09 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 (40)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication MAGNESIUM OXIDE

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

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 (40)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)		02 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 (41)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication MELATONIN

Prophylaxis Yes ☒
No ☐

Indication GENERAL HEALTH

Dose per administration 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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication METHOCARBAMOL

Prophylaxis Yes ☐
No ☒

Indication MUSCLE SPASMS, MOTOR
VEHICLE ACCIDENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)		07 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)		3
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication PANTOPRAZOLE

Prophylaxis Yes ☐
No ☒

Indication GASTROESOPHAGEAL REFLUX
DISEASE

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 ☐

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EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intraocular	<input type="checkbox"/>
	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		03 NOV 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="radio"/>
	No	<input type="radio"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input checked="" type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication PAROXETINE

Prophylaxis Yes ☐
No ☒

Indication ANXIETY

Dose per administration 20

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)	02 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)	01 FEB 2021	
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)	1	
Interval Dosage Unit Number (derived)	1	
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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Name of Medication RENAL MULTIVITAMIN

Prophylaxis Yes ☒
No ☐

Indication KIDNEY GENERAL HEALTH

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 (45)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

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Name of Medication ACETAMINOPHEN

Prophylaxis Yes ☒
No ☐

Indication PAIN, MOTOR VEHICLE
ACCIDENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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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)	02 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)		
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 (47)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication BISACODYL

Prophylaxis Yes ☒
No ☐

Indication CONSTIPATION PREVENTION

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)

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify		SUPPOSITORY
Start date (dd MMM yyyy)	02 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)		01 FEB 2021
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication DEXTROSE GEL 40%

Prophylaxis Yes ☐
No ☒

Indication HYPOGLYCEMIA

Dose per administration 15

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 (48)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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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)		02 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)		09 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 (49)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication DEXTROSE SOLUTION 50%

Prophylaxis Yes ☐
No ☒

Indication HYPOGLYCEMIA

Dose per administration 12.5

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 (49)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 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)		09 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 (50)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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Name of Medication DEXTROSE SOLUTION 50%

Prophylaxis Yes ☐
No ☒

Indication HYPOGLYCEMIA

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 (50)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input checked="" type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		02 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)		09 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 (51)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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Name of Medication GLUCAGON

Prophylaxis Yes ☐
No ☒

Indication HYPOGLYCEMIA

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 (51)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)	02 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)		09 DEC 2020
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived) _____		
Interval Dosage Unit Number (derived) _____		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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Name of Medication IPRATROPIUM-ALBUTEROL

Prophylaxis Yes ☐
No ☒

Indication COUGH

Dose per administration .5-2.5/3

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

If dose unit is Other, specify MG/ML

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRANASAL	
Start date (dd MMM yyyy)	02 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)	09 DEC 2020	
Was this medication taken for solicited event?	Yes	<input type="radio"/>
	No	<input checked="" type="radio"/>
Separate Dosage Number (derived)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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Name of Medication ODASETRON ODT

Prophylaxis Yes ☐
No ☒

Indication NAUSEA

Dose per administration 4

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)		02 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)		09 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 (54)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication SODIUM CHLORIDE

Prophylaxis Yes ☐
No ☒

Indication HPONATREMIA

Dose per administration 0.65%

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 (54)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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	Intramuscular	<input type="radio"/>
	Respiratory (Inhalation)	<input type="radio"/>
	Intralesional	<input type="radio"/>
	Intraperitoneal	<input type="radio"/>
	Nasal	<input type="radio"/>
	Vaginal	<input type="radio"/>
	Rectal	<input type="radio"/>
	Intravenous	<input type="radio"/>
	Intravenous Bolus	<input type="radio"/>
	Intravenous Drip	<input type="radio"/>
	Other	<input checked="" type="radio"/>
If route of administration is Other, specify	INTRANSAL	
Start date (dd MMM yyyy)	02 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)		
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 (55)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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Name of Medication HYDROCODONE/ACETAMINOP
HEN

Prophylaxis Yes ☐
No ☒

Indication PAIN, MOTOR VEHICLE
ACCIDENT

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 ☐

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Data signed: (b) (4) 16 Apr 2021 13:30:17

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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)		02 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)		_____
Interval Dosage Unit Number (derived)		_____
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication OXYCODONE/ACETAMINOPHE
N

Prophylaxis Yes ☐
No ☒

Indication PAIN, MOTOR VEHICLE
ACCIDENT

Dose per administration 3/325

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)	02 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication DICLOFENAC 1%

Prophylaxis Yes ☐
No ☒

Indication PAIN, MOTOR VEHICLE
ACCIDENT

Dose per administration 1

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

If dose unit is Other, specify APPLICATION

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

If frequency is Other, specify

Route of administration Oral ☐
Topical ☒
Subcutaneous ☐
Transdermal ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)		01 OCT 2020
Start date completely unknown		False
Ongoing?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy)		09 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"/>

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication TYLENOL

Prophylaxis Yes ☐
No ☒

Indication PAIN, MOTOR VEHICLE
ACCIDENT

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 ☐

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	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)	08 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)		
Interval Dosage Unit Number (derived)		
Interval Dosage Definition (derived)	802	<input type="radio"/>
	803	<input type="radio"/>
	804	<input type="radio"/>

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

Name of Medication BREO

Prophylaxis Yes ☐
No ☒

Indication COUGH

Dose per administration 1

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

If dose unit is Other, specify

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

If frequency is Other, specify

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

PRODUCTION RELEASE (v12.003
EAB) (1725)

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Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Data signed: (b) (4) 16 Apr 2021 13:30:17

Generated On: 09 Jun 2021 17:32:44

	Intramuscular	<input type="checkbox"/>
	Respiratory (Inhalation)	<input checked="" type="checkbox"/>
	Intralesional	<input type="checkbox"/>
	Intraperitoneal	<input type="checkbox"/>
	Nasal	<input type="checkbox"/>
	Vaginal	<input type="checkbox"/>
	Rectal	<input type="checkbox"/>
	Intravenous	<input type="checkbox"/>
	Intravenous Bolus	<input type="checkbox"/>
	Intravenous Drip	<input type="checkbox"/>
	Other	<input type="checkbox"/>
If route of administration is Other, specify _____		
Start date (dd MMM yyyy)		08 SEP 2020
Start date completely unknown		False
Ongoing?	Yes	<input checked="" type="checkbox"/>
	No	<input type="checkbox"/>
If not Ongoing, End date (dd MMM yyyy) _____		
Was this medication taken for solicited event?	Yes	<input type="checkbox"/>
	No	<input checked="" type="checkbox"/>
Separate Dosage Number (derived)		1
Interval Dosage Unit Number (derived)		1
Interval Dosage Definition (derived)	802	<input type="checkbox"/>
	803	<input type="checkbox"/>
	804	<input checked="" type="checkbox"/>

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Data signed: (b) (4) 12 Apr 2021 14:34:56

Generated On: 09 Jun 2021 17:32:44

Were any concomitant procedures performed?

Yes ☒

No ☐

If yes, please complete Concomitant Procedures form.

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Folder: Concomitant Procedures (1)

Form: Concomitant Procedures

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (dd MMM yyyy)	Procedure/Surgery	Indication	If indication is Other, specify
18 SEP 2020	TRACHESTOMY	Adverse Event	
18 SEP 2020	BRONCHOSCOPY	Adverse Event	
18 SEP 2020	PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBE PLACEMENT	Adverse Event	
13 SEP 2020	CLOSED RIGHT TIBIA-FIBULA FRACTURE	Adverse Event	
23 SEP 2020	BLOOD TRANSFUSION	Adverse Event	
18 SEP 2020	VENTILATORY SUPPORT	Adverse Event	
UN SEP 2020	ENTERAL NUTRITION	Adverse Event	
14 SEP 2020	HEAD CT	Adverse Event	
10 SEP 2020	PLACEMENT OF EXTRAVENTRICULAR DRAINS	Adverse Event	
UN SEP 2020	HEAD MRI	Adverse Event	
UN SEP 2020	TTE	Adverse Event	

US3412125

Folder: End of Study (1)

Form: Dosing Discontinuation

Generated On: 09 Jun 2021 17:32:44

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

US3412125

Folder: End of Study (1)

Form: End of Study / Study Discontinuation

Generated On: 09 Jun 2021 17:32:44

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 ☐

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	10/SEP/2020 12:59
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	22/SEP/2020 09:09
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	19/OCT/2020 14:07
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	20/OCT/2020 12:43
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	21/OCT/2020 13:55
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	22/OCT/2020 13:07
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	23/OCT/2020 16:05
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	11/NOV/2020 17:50
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	19/NOV/2020 13:56
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (10)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	25/NOV/2020 20:36
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (11)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	27/NOV/2020 13:01
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (12)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	18/DEC/2020 13:24
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (13)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	16/FEB/2021 15:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (14)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	22/FEB/2021 10:35
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (15)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	07/APR/2021 10:49
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (16)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	07/APR/2021 12:15
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (17)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	09/APR/2021 13:39
Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.	True

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (18)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	20/APR/2021 10:43
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

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (19)

Data signed: (b) (4) 26 Apr 2021 14:40:17

Generated On: 09 Jun 2021 17:32:44

SAEID	USA-US061-2020-MRNA-1273-P301000005
Serious	Yes <input checked="" type="radio"/> No <input type="radio"/>
Death	Yes <input type="radio"/> No <input checked="" type="radio"/>
Life threatening	Yes <input checked="" type="radio"/> No <input type="radio"/>
Requires inpatient or prolongation of existing Hospitalization	Yes <input checked="" type="radio"/> No <input type="radio"/>
Persistent or significant disability or incapacity	Yes <input type="radio"/> No <input checked="" type="radio"/>
Congenital anomaly or birth defect	Yes <input type="radio"/> No <input checked="" type="radio"/>
Other medically important event	Yes <input type="radio"/> No <input checked="" type="radio"/>
Investigator's First Name	RICHARD
Investigator's Last Name	POWELL
Site Address: Street	
Site Address: City	
Site Address: State	OH
Site Address: Postal Code	
Investigator Country	US
E2B Transmit Flag (Derived/Hidden)	19
Date of submission (Pre-filled from custom function)	21/APR/2021 06:06
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

Audit

US3412125 (Prod: New Horizons Clinical Research)

US3412125

Form: Participant Creation

Generated On: 09 Jun 2021 17:32:44

[Participant ID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'US3412125'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:29:36

US3412125

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'Yes (Y)'	Steven Anderson (b) (4)	04 Aug 2020 19:51:37

US3412125

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:29:38

US3412125

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	04 Aug 2020 19:51:37

US3412125

Folder: Screening

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'SCRN'	System	04 Aug 2020 19:51:37

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

Date of Birth (MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered (b) (6) 1949'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:29:39

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[Age](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '71'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[Age Units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'YEARS'	System	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[Age \(Derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '71'	System	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[Sex](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Female (F)'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[Ethnicity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Not Hispanic or Latino (NOT HISPANIC OR LATINO)'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

White

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'I'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[Black](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[Asian](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[American Indian or Alaska Native](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[Native Hawaiian or other Pacific Islander](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

If race is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[Unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Demographics

Generated On: 09 Jun 2021 17:32:44

[Not reported](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	04 Aug 2020 19:51:51

US3412125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:32:44

Date of Informed Consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '04 Aug 2020'	Steven Anderson (b) (4)	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Aug 2020'	System	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2020'	System	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:32:44

[Protocol Version](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Amendment 1 (1)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:32:44

If No, indicate reason for screen fail

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:32:44

If reason for screen fail is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:32:44

[Was this participant screened previously?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'No (N)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:07

US3412125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:32:44

[If Yes, previous participant number](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 18:29:38

US3412125

Folder: Screening

Form: Enrollment

Generated On: 09 Jun 2021 17:32:44

[Enrollment Trigger](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'I'	System	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Inclusion/Exclusion Criteria Summary

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Medical History Summary

Generated On: 09 Jun 2021 17:32:44

[Were any significant conditions reported?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:51:37

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:32:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User coded data point as SOC: Endocrine disorders, HLT: Thyroid gland disorders, HLT: Thyroid hypofunction disorders, PT: Hypothyroidism, LLT: Hypothyroidism - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:54:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:54:16
Data point term sent to Coder	System	11 Aug 2020 12:52:56
User entered 'Hypothyroid'	Steven Anderson (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'un UNK 2009'	Steven Anderson (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2009'	System	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2009'	System	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:52:08

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:32:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User coded data point as SOC: Vascular disorders, HLT: Vascular hypertensive disorders, HLT: Vascular hypertensive disorders NEC, PT: Hypertension, LLT: Hypertension - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:54:16
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:54:16
Data point term sent to Coder	System	11 Aug 2020 12:52:56
User entered 'Hypertension'	Steven Anderson (b) (4)	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'un UNK 2018'	Steven Anderson (b) (4)	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:32:44

Start Month and Year (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2018'	System	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2018'	System	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:52:23

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:32:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 07:49:43
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	12 Nov 2020 07:49:43
Data point term sent to Coder	System	22 Oct 2020 14:03:42
Coding entries removed.	Mylene Asmar-Rios	22 Oct 2020 14:03:24
User entered 'IBS-O' reason for change: Data Entry Error	(b) (4)	
	Mylene Asmar-Rios	22 Oct 2020 14:03:24
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal spastic and hypermotility disorders, PT: Irritable bowel syndrome, LLT: Diarrhea predominant irritable bowel syndrome - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:06:13
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	14 Aug 2020 08:06:13
Data point term sent to Coder	System	11 Aug 2020 12:52:58
User entered 'IBS-D'	Steven Anderson (b) (4)	11 Aug 2020 12:52:52
	(b) (4)	

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'un UNK 2000'	Steven Anderson (b) (4)	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2000'	System	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2000'	System	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:52:52

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:32:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Spinal osteoarthritis, LLT: Spinal osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:28:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	24 Nov 2020 18:28:42
Data point term sent to Coder	System	22 Sep 2020 12:58:11
Coding entries removed.	Melissa Fuson (b) (4)	22 Sep 2020 12:57:12
User entered 'OSTEOARTHRITIS - back (low back)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Sep 2020 12:57:12
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Osteoarthropathies, PT: Osteoarthritis, LLT: Osteoarthritis - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:55:08
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:55:08
Data point term sent to Coder	System	11 Aug 2020 12:53:59
User entered 'Osteoarthritis'	Steven Anderson (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'un UNK 2014'	Steven Anderson (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2014'	System	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2014'	System	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:53:18

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:32:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
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)	03 Oct 2020 09:27:42
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	03 Oct 2020 09:27:42
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Musculoskeletal and connective tissue disorders NEC, HLT: Musculoskeletal and connective tissue pain and discomfort, PT: Back pain, LLT: Chronic back pain - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:56:14
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	11 Aug 2020 12:56:14
Data point term sent to Coder	System	11 Aug 2020 12:55:01
User entered 'Chronic Lower Back Pain'	Steven Anderson (b) (4)	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'UN UNK 2009' reason for change:	(b) (4)	
Data Entry Error	Mylene Asmar-Rios	05 Nov 2020 20:57:03
User entered 'un UNK 2014'	(b) (4)	
	Steven Anderson (b) (4)	11 Aug 2020 12:54:01
	(b) (4)	

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2009'	System	05 Nov 2020 20:57:03
User entered 'Jan 2014'	System	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2009'	System	05 Nov 2020 20:57:03
User entered '2014'	System	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:54:01

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:32:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis media, LLT: Otitis media serous - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 10:05:08
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	23 Nov 2020 10:05:08
Data point term sent to Coder	System	22 Sep 2020 12:59:12
Coding entries removed.	Melissa Fuson (b) (4)	22 Sep 2020 12:59:00
User entered 'NON ACUTE SEROUS OTITIS MEDIA (non-infectious) "fluid in ear" (bilateral)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	22 Sep 2020 12:59:00
User coded data point as SOC: Infections and infestations, HLGT: Infections - pathogen unspecified, HLT: Ear infections, PT: Otitis media acute, LLT: Otitis media acute - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 13:57:17
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	19 Aug 2020 13:57:17
Data point term sent to Coder	System	11 Aug 2020 12:55:01
User entered 'Non acute Serous otitis media'	Steven Anderson (b) (4)	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'un UNK 2000'	Steven Anderson (b) (4)	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2000'	System	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2000'	System	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	11 Aug 2020 12:54:28

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:32:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User coded data point as SOC: Musculoskeletal and connective tissue disorders, HLGT: Joint disorders, HLT: Joint related signs and symptoms, PT: Arthralgia, LLT: Arthralgia multiple - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 15:04:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	22 Sep 2020 15:04:02
Data point term sent to Coder	System	22 Sep 2020 13:01:16
User entered 'Intermittent Joint Pain (elbows / ankles, occasional knees / hips)'	Melissa Fuson (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'un UNK 2010'	Melissa Fuson (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Melissa Fuson (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Melissa Fuson (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Melissa Fuson (b) (4)	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2010'	System	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2010'	System	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	22 Sep 2020 13:00:34

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:32:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User coded data point as SOC: Social circumstances, HLT: Age related factors, HLT: Age related issues, PT: Postmenopause, LLT: Postmenopause - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 18:07:27
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	09 Oct 2020 18:07:27
Data point term sent to Coder	System	09 Oct 2020 18:06:37
User entered 'post menopausal'	Jacob sekinger (b) (4)	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'un UNK 2005'	Jacob sekinger (b) (4)	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Jacob sekinger (b) (4)	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Jacob sekinger (b) (4)	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Jacob sekinger (b) (4)	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Jacob sekinger (b) (4)	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2005'	System	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2005'	System	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (8)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	09 Oct 2020 18:06:22

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:32:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal motility and defaecation conditions, HLT: Gastrointestinal atonic and hypomotility disorders NEC, PT: Gastrooesophageal reflux disease, LLT: GERD - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 14:25:37
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	22 Oct 2020 14:25:37
Data point term sent to Coder	System	22 Oct 2020 14:01:39
User entered 'GERD'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'UN UNK 2009'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	(b) (4) Mylene Asmar-Rios	22 Oct 2020 14:01:11
	(b) (4)	

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2009'	System	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2009'	System	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (9)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered empty.	System	22 Oct 2020 14:01:11

US3412125

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:32:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Hernia repairs, PT: Abdominal hernia repair, LLT: Abdominal hernia repair - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:57:44
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	17 Dec 2020 16:57:44
Data point term sent to Coder	System	17 Dec 2020 16:56:42
User entered 'ABDOMINAL HERNIA REPAIR'	Melissa Fuson (b) (4)	17 Dec 2020 16:56:39

US3412125

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'UN UNK 2018'	Melissa Fuson (b) (4)	17 Dec 2020 16:56:39

US3412125

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Melissa Fuson (b) (4)	17 Dec 2020 16:56:39

US3412125

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Dec 2020 16:56:39

US3412125

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'UN UNK 2018'	Melissa Fuson (b) (4)	17 Dec 2020 16:56:39

US3412125

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Melissa Fuson (b) (4)	17 Dec 2020 16:56:39

US3412125

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2018'	System	17 Dec 2020 16:56:39

US3412125

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2018'	System	17 Dec 2020 16:56:39

US3412125

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2018'	System	17 Dec 2020 16:56:39

US3412125

Folder: Screening

Form: Medical History (10)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2018'	System	17 Dec 2020 16:56:39

US3412125

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:32:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User closed query 'Per DM CLR: Please indicate underlying medical condition which lead to this procedure, update all necessary eCRF page.' (Site from DM).		15 Apr 2021 15:52:15
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate.' (Site from DM).		15 Apr 2021 15:52:14
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Gastrointestinal therapeutic procedures NEC, PT: Enterorrhaphy, LLT: Intestinal perforation repair - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:29:54
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	14 Apr 2021 14:29:54
Data point term sent to Coder	System	13 Apr 2021 20:20:32
User closed query 'CDM coding: Please split the reported term RUPTURED DIVERTICULUM REPAIR and report on separate loglines to capture coding for both the terms. Example: 1) RUPTURED DIVERTICULUM and 2) RUPTURED DIVERTICULUM REPAIR' (Site from System).	System	13 Apr 2021 20:19:59
Query 'CDM coding: Please split the reported term RUPTURED DIVERTICULUM REPAIR and report on separate loglines to capture coding for both the terms. Example: 1) RUPTURED DIVERTICULUM and 2) RUPTURED DIVERTICULUM REPAIR' answered with 'Hello bowel obstruction was the issue and caused this surgery. this has been added to medical conditions' (Site from System).	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 20:19:59
Query 'Per DM CLR: Please indicate underlying medical condition which lead to this procedure, update all necessary eCRF page.' answered with 'associated condition has been updated' (Site from DM).	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 20:19:15

US3412125

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:32:44

Condition

Audit	User	Time (GMT)
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'associtaed condition has been added' (Site from DM).	Steven Anderson (b) (4)	13 Apr 2021 20:19:00
User opened query 'CDM coding: Please split the reported term RUPTURED DIVERTICULUM REPAIR and report on separate loglines to capture coding for both the terms. Example: 1) RUPTURED DIVERTICULUM and 2) RUPTURED DIVERTICULUM REPAIR' (Site from System).	Coder Import (b) (4)	24 Mar 2021 10:04:32
User opened query 'Per DM CLR: Please indicate underlying medical condition which lead to this procedure, update all necessary eCRF page.' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:53:37
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:52:32
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
Data point term sent to Coder	(b) (4) System	18 Feb 2021 16:07:38
User entered 'ruptured diverticulum repair'	Andrea Newlands (b) (4) (b) (4)	18 Feb 2021 16:07:23

US3412125

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'un UNK 2016'	Andrea Newlands (b) (4)	18 Feb 2021 16:07:23

US3412125

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered '0'	Andrea Newlands (b) (4)	18 Feb 2021 16:07:23

US3412125

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'No (N)'	Andrea Newlands (b) (4)	18 Feb 2021 16:07:23

US3412125

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'un UNK 2016'	Andrea Newlands (b) (4)	18 Feb 2021 16:07:23

US3412125

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered '0'	Andrea Newlands (b) (4)	18 Feb 2021 16:07:23

US3412125

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2016'	System	18 Feb 2021 16:07:23

US3412125

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2016'	System	18 Feb 2021 16:07:23

US3412125

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2016'	System	18 Feb 2021 16:07:23

US3412125

Folder: Screening

Form: Medical History (11)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2016'	System	18 Feb 2021 16:07:23

US3412125

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:32:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).		15 Apr 2021 15:52:24
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'ileostomy was because of the surgery' (Site from DM).	Steven Anderson (b) (4)	13 Apr 2021 20:20:53
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:53:55
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Ileostomy, LLT: Ileostomy - version MedDRA\23.0.	Coder Import (b) (4)	18 Feb 2021 16:25:59
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	18 Feb 2021 16:25:59
Data point term sent to Coder	System	18 Feb 2021 16:08:40
User entered 'ileostomy'	Andrea Newlands (b) (4)	18 Feb 2021 16:07:54

US3412125

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'un UNK 2016'	Andrea Newlands (b) (4)	18 Feb 2021 16:07:54

US3412125

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered '0'	Andrea Newlands (b) (4)	18 Feb 2021 16:07:54

US3412125

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'No (N)'	Andrea Newlands (b) (4)	18 Feb 2021 16:07:54

US3412125

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'un UNK 2016'	Andrea Newlands (b) (4)	18 Feb 2021 16:07:54

US3412125

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered '0'	Andrea Newlands (b) (4)	18 Feb 2021 16:07:54

US3412125

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2016'	System	18 Feb 2021 16:07:54

US3412125

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2016'	System	18 Feb 2021 16:07:54

US3412125

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2016'	System	18 Feb 2021 16:07:54

US3412125

Folder: Screening

Form: Medical History (12)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2016'	System	18 Feb 2021 16:07:54

US3412125

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:32:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User closed query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).		15 Apr 2021 15:52:31
Query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' answered with 'ileostomy was reversed for the subject due to being medically cleared for the surgery from the ileostomy' (Site from DM).	Steven Anderson (b) (4)	13 Apr 2021 20:22:25
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Small intestine therapeutic procedures, PT: Ileostomy, LLT: Ileostomy revision - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 10:09:58
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4)	15 Mar 2021 10:09:58
User opened query 'Per DM CLR: Please review and ensure the associated condition which led to this procedure is also captured in the Med History eCRF (please enter associated condition in a separate entry). Please verify and update as appropriate. ' (Site from DM).	(b) (4), (b) (6)	27 Feb 2021 15:54:08
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
Data point term sent to Coder	System	18 Feb 2021 16:08:40
User entered 'ileostomy reversal'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:15

US3412125

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'un UNK 2017'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:15

US3412125

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered '0'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:15

US3412125

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'No (N)'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:15

US3412125

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'un UNK 2017'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:15

US3412125

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered '0'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:15

US3412125

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2017'	System	18 Feb 2021 16:08:15

US3412125

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2017'	System	18 Feb 2021 16:08:15

US3412125

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2017'	System	18 Feb 2021 16:08:15

US3412125

Folder: Screening

Form: Medical History (13)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2017'	System	18 Feb 2021 16:08:15

US3412125

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:32:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Head and neck therapeutic procedures, HLT: Tonsillar therapeutic procedures, PT: Tonsillectomy, LLT: Tonsillectomy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:10:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:10:52
Data point term sent to Coder	System	18 Feb 2021 16:09:41
User entered 'tonsillectomy'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:58

US3412125

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'un UNK 1963'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:58

US3412125

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered '0'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:58

US3412125

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'No (N)'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:58

US3412125

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'un UNK 1963'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:58

US3412125

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered '0'	Andrea Newlands (b) (4)	18 Feb 2021 16:08:58

US3412125

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 1963'	System	18 Feb 2021 16:08:58

US3412125

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '1963'	System	18 Feb 2021 16:08:58

US3412125

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 1963'	System	18 Feb 2021 16:08:58

US3412125

Folder: Screening

Form: Medical History (14)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '1963'	System	18 Feb 2021 16:08:58

US3412125

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:32:44

Condition

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:40:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:40:52
User coded data point as SOC: Surgical and medical procedures, HLGT: Gastrointestinal therapeutic procedures, HLT: Large intestine therapeutic procedures, PT: Appendectomy, LLT: Appendectomy - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:10:52
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4)	18 Feb 2021 16:10:52
Data point term sent to Coder	System	18 Feb 2021 16:09:41
User entered 'appendectomy'	Andrea Newlands (b) (4)	18 Feb 2021 16:09:16

US3412125

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'un UNK 1979'	Andrea Newlands (b) (4)	18 Feb 2021 16:09:16

US3412125

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered '0'	Andrea Newlands (b) (4)	18 Feb 2021 16:09:16

US3412125

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'No (N)'	Andrea Newlands (b) (4)	18 Feb 2021 16:09:16

US3412125

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered 'un UNK 1979'	Andrea Newlands (b) (4)	18 Feb 2021 16:09:16

US3412125

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	19 Feb 2021 03:55:41
User entered '0'	Andrea Newlands (b) (4)	18 Feb 2021 16:09:16

US3412125

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 1979'	System	18 Feb 2021 16:09:16

US3412125

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '1979'	System	18 Feb 2021 16:09:16

US3412125

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 1979'	System	18 Feb 2021 16:09:16

US3412125

Folder: Screening

Form: Medical History (15)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '1979'	System	18 Feb 2021 16:09:16

US3412125

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:32:44

[Condition](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as SOC: Gastrointestinal disorders, HLGT: Gastrointestinal stenosis and obstruction, HLT: Gastrointestinal stenosis and obstruction NEC, PT: Intestinal obstruction, LLT: Bowel obstruction - version MedDRA\\23.0.	(b) (4) Coder Import (b) (4) (b) (4)	13 Apr 2021 20:20:29
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	13 Apr 2021 20:20:29
Data point term sent to Coder	System	13 Apr 2021 20:18:30
User entered 'bowel obstruction'	Steven Anderson (b) (4) (b) (4)	13 Apr 2021 20:18:28

US3412125

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'un UNK 2016'	Steven Anderson (b) (4)	13 Apr 2021 20:18:28

US3412125

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Steven Anderson (b) (4)	13 Apr 2021 20:18:28

US3412125

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:32:44

[Condition ongoing at study entry](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Steven Anderson (b) (4)	13 Apr 2021 20:18:28

US3412125

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'un UNK 2016'	Steven Anderson (b) (4)	13 Apr 2021 20:18:28

US3412125

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:32:44

[Stop date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Steven Anderson (b) (4)	13 Apr 2021 20:18:28

US3412125

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2016'	System	13 Apr 2021 20:18:28

US3412125

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2016'	System	13 Apr 2021 20:18:28

US3412125

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'Jan 2016'	System	13 Apr 2021 20:18:28

US3412125

Folder: Screening

Form: Medical History (16)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '2016'	System	13 Apr 2021 20:18:28

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered '04 Aug 2020'	Steven Anderson (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered '14:35'	Steven Anderson (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered '04 Aug 2020 14:35'	System	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Height (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered '158.0' cm	Steven Anderson (b) (4)	11 Aug 2020 12:56:19
DataPoint set to visible.	System	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Weight (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered '54.7' kg	Steven Anderson (b) (4)	11 Aug 2020 12:56:19
DataPoint set to visible.	System	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

BMI (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
Amendment Manager: User entered '21.91155'	System	16 Sep 2020 23:42:52
User entered '21.9'	System	11 Aug 2020 12:56:19
DataPoint set to visible.	System	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[BMI units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'kg/m2'	System	11 Aug 2020 12:56:19
DataPoint set to visible.	System	04 Aug 2020 19:52:13

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:48:32
User entered '36.7' C	Steven Anderson (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered empty; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:48:32
User entered 'Oral (Oral)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:48:32
User entered '70'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'bpm'	System	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:48:32
User entered '14'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'breaths/min'	System	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:48:32
User entered '124'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'mmHg'	System	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered missing code ND - Not Done; reason for change Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:48:32
User entered '68'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User entered 'mmHg'	System	11 Aug 2020 12:56:19

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Height \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01

US3412125

Folder: Screening

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Weight (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01

US3412125

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:32:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:56:41

US3412125

Folder: Screening

Form: Physical Examination

Generated On: 09 Jun 2021 17:32:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
Query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	07 Sep 2020 08:57:03
User opened query 'The Physical Examination Date is prior to the Screening Visit Date. Please review and reconcile.' (Site from System).	System	01 Sep 2020 16:25:11
User entered '04 Aug 2020'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:56:41

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:32:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '04 Aug 2020'	Steven Anderson (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:32:44

[Is the participant of childbearing potential?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:32:44

If No, what is the reason?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
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).	(b) (4) (b) (4), (b) (6)	21 Oct 2020 06:05:59
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 'updated. ' (Site from DM).	Jacob sekinger (b) (4) (b) (4)	09 Oct 2020 18:07:49
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)	08 Oct 2020 05:05:05
User entered 'Post-menopausal (POST-MENOPAUSAL)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:32:44

If Partner medically sterile or Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:32:44

[Date of surgery unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:32:44

If Post-menopausal, date of last menstruation (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'un UNK 2005'	Steven Anderson (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Childbearing Potential

Generated On: 09 Jun 2021 17:32:44

[Date of last menstruation unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:57:15

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

Retail or Restaurant Operations, particularly those in critical and/high-customer volume (e.g., grocery, convenience, hardware, big-box stores)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

Manufacturing & Production Operations with inherent overcrowding (e.g., factory workers, meat/food processing plants)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

Warehouse shipping and fulfillment centers and jobs (e.g., Amazon facilities)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

[Transportation and delivery services](#) (e.g., airlines, public transit, taxi/UBER, fed ex/UPS, postal workers)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

Border Protection and Military Personnel (e.g., TSA, custom and border protection agents, military personnel not social distancing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

Personal Care and in-home services (e.g., barber/salon/spa, in-home repair services, electricians, plumbers, janitorial services)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

[Hospitality and Tourism Workers](#) (e.g., hotel, casino, amusement/theme park, entertainment, ski resorts)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

Pastoral, Social or Public Health Workers requiring frequent contact with community members (e.g., social workers, volunteers, religious clergy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

Educators and Students (e.g., teachers, administrators, support staff, and students interacting in face-to-face school setting)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

No Risk Identified

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

[Resides in Nursing Home or Assisted Living Facility](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

Resides in Multi-family dwelling (e.g., cohabitation in dwelling with > 5 people, includes grandparents living with children < 18yrs)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

Resides in high density housing (e.g., high rise apartments with shared entrances or elevators)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

Resides in low density, multi-family setting without (e.g., apartments complex without shared entrances or elevators, duplexes)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered '0'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

[Resides in a single family home](#) (i.e., detached housing)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'I'	Steven Anderson (b) (4)	11 Aug 2020 12:57:47

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

[Other](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	22 Sep 2020 13:14:38
User entered '0'	(b) (4)	
	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Screening

Form: Risk of Exposure

Generated On: 09 Jun 2021 17:32:44

[Specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:47:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:36
User entered 'Lives in High Risk County' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	22 Sep 2020 13:14:38
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	11 Aug 2020 12:57:47
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:28

US3412125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '04 Aug 2020'	Steven Anderson (b) (4)	04 Aug 2020 19:52:28

US3412125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:28

US3412125

Folder: Visit 1 Day 1

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'VISIT1'	System	04 Aug 2020 19:52:28

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '04 AUG 2020'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:44:26

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:44

[What was the participant's randomization number?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
Amendment Manager: User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	21 Aug 2020 02:02:25
Amendment Manager: Data point set to conformant.	System	21 Aug 2020 02:02:25
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	04 Aug 2020 19:44:26
User entered '184599' (non-conformant).	RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:44:26

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:44

[In what Cohort was the participant enrolled?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '>=65 years (3)'	(b) (4) RWS_ENDPOINT ENDPOINT (b) (4)	04 Aug 2020 19:44:26

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:44

Chronic lung disease (eg, emphysema and chronic bronchitis, idiopathic pulmonary fibrosis and cystic fibrosis, or moderate to severe asthma)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'No (N)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:41

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:44

Significant cardiac disease (eg, heart failure, coronary artery disease, congenital heart disease, cardiomyopathies, and pulmonary hypertension)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'No (N)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:41

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:44

Severe obesity (body mass index > or = 40kg/m2

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'No (N)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:41

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:44

Diabetes (Type I, Type 2, or gestational)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'No (N)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:41

US3412125

Folder: Visit 1 Day 1

Form: Randomization

Generated On: 09 Jun 2021 17:32:44

[Liver Disease](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'No (N)'	Steven Anderson (b) (4)	04 Aug 2020 19:52:41

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered 'No (N)'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '4 Aug 2020' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '14:35' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered '4 Aug 2020 14:35'	System	21 Aug 2020 15:50:24
User entered empty.	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '36.7' C reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Oral (Oral)' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '70' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'bpm'	System	21 Aug 2020 15:50:24
User entered empty.	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '14' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'breaths/min'	System	21 Aug 2020 15:50:24
User entered empty.	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '124' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'mmHg'	System	21 Aug 2020 15:50:24
User entered empty.	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '68' reason for change: Data Entry Error	(b) (4) (b) (4), (b) (6)	21 Aug 2020 15:50:24
User entered empty.	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'mmHg'	System	21 Aug 2020 15:50:24
User entered empty.	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:44

[Height](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing

Generated On: 09 Jun 2021 17:32:44

Weight

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered missing code ND - Not Done.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '04 Aug 2020'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
Query 'Post-dose vital signs time is prior to or less than 60 minutes after the Dose Time. Please review and reconcile.' canceled (Site from System).	(b) (4) (b) (4), (b) (6)	17 Aug 2020 17:50:45
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).		11 Aug 2020 12:59:27
User entered '16:26'	Steven Anderson (b) (4) (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered '04 Aug 2020 16:26'	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '97.4' F	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '68'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'bpm'	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '14'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'breaths/min'	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User closed query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	(b) (4), (b) (6)	21 Aug 2020 19:01:30
Query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' answered with 'NCS' (Site from System).		21 Aug 2020 15:51:01
User opened query 'Systolic Blood Pressure reported is out of range < 80 or > 155 per protocol considered grade 3. Please indicate if CS/NCS and report as AE, if appropriate.' (Site from System).	System	11 Aug 2020 12:59:27
User entered '158'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'mmHg'	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '72'	Steven Anderson (b) (4)	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'mmHg'	System	11 Aug 2020 12:59:27

US3412125

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:32:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 13:00:12

US3412125

Folder: Visit 1 Day 1

Form: Physical Examination

Generated On: 09 Jun 2021 17:32:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 13:00:12

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

If No, reason not given

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered empty.	Steven Anderson (b) (4)	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered empty.	Steven Anderson (b) (4)	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'MRNA-1273 OR PLACEBO'	System	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '04 Aug 2020'	Steven Anderson (b) (4)	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '15:55'	Steven Anderson (b) (4)	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered '04 Aug 2020 15:55'	System	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'ONCE'	System	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'INTRAMUSCULAR'	System	04 Aug 2020 20:00:44

US3412125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 13:02:11

US3412125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '04 Aug 2020'	Steven Anderson (b) (4)	11 Aug 2020 13:02:11

US3412125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '15:28'	(b) (4)	11 Aug 2020 13:02:11
	Steven Anderson (b) (4)	
	(b) (4)	

US3412125

Folder: Visit 1 Day 1

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered '04 Aug 2020 15:28'	System	11 Aug 2020 13:02:11

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:32:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '04 Aug 2020'	Steven Anderson (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:32:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:32:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:32:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '15:34'	Steven Anderson (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:32:44

Collection date and time (derived)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered '04 Aug 2020 15:34'	System	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:32:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:32:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:32:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered empty.	Steven Anderson (b) (4)	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:32:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered empty.	System	11 Aug 2020 13:03:20

US3412125

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	11 Aug 2020 13:03:28

US3412125

Folder: Visit 1 Day 1

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'I'	System	11 Aug 2020 13:03:28

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:33:59', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4fc55baa-c5b5-435d-8798-3af5a9634053'	System	04 Aug 2020 20:34:59
User entered 'Yes (Y)'	System	04 Aug 2020 20:34:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:34:14', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4fc55baa-c5b5-435d-8798-3af5a9634053' User entered '97.4'	System	04 Aug 2020 20:34:59
	System	04 Aug 2020 20:34:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:34:34', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4fc55baa-c5b5-435d-8798-3af5a9634053' User entered 'No (N)'	System	04 Aug 2020 20:34:59
	System	04 Aug 2020 20:34:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:34:54', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4fc55baa-c5b5-435d-8798-3af5a9634053'	System	04 Aug 2020 20:34:59
User entered '04 Aug 2020 16:34'	System	04 Aug 2020 20:34:59

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Aug 2020 16:15'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Aug 2020 18:45'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:08:44', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'db819a99-2cb1-4766-bee9-0250ceefe29a' User entered 'Yes (Y)'	System	05 Aug 2020 00:09:20
	System	05 Aug 2020 00:09:20

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'db819a99-2cb1-4766-bee9-0250ceefe29a' User entered '96.6'	System	05 Aug 2020 00:09:20
	System	05 Aug 2020 00:09:20

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:06', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'db819a99-2cb1-4766-bee9-0250ceefe29a'	System	05 Aug 2020 00:09:20
User entered 'No (N)'	System	05 Aug 2020 00:09:20

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'db819a99-2cb1-4766-bee9-0250ceefe29a' User entered '04 Aug 2020 20:09'	System	05 Aug 2020 00:09:20
	System	05 Aug 2020 00:09:20

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Aug 2020 19:40'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 2'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:38:30', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'b88e7c59-3960-47ee-baac-182065971304' User entered 'Yes (Y)'	System	05 Aug 2020 23:39:02
	System	05 Aug 2020 23:39:02

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:38:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'b88e7c59-3960-47ee-baac-182065971304' User entered '95.5'	System	05 Aug 2020 23:39:02
	System	05 Aug 2020 23:39:02

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:38:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'b88e7c59-3960-47ee-baac-182065971304'	System	05 Aug 2020 23:39:02
User entered 'No (N)'	System	05 Aug 2020 23:39:02

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'b88e7c59-3960-47ee-baac-182065971304'	System	05 Aug 2020 23:39:02
User entered '05 Aug 2020 19:39'	System	05 Aug 2020 23:39:02

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 3'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:44:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '60db8904-c049-48c1-82bf-87ff24e101b6'	System	06 Aug 2020 23:45:09
User entered 'Yes (Y)'	System	06 Aug 2020 23:45:09

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:44:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '60db8904-c049-48c1-82bf-87ff24e101b6' User entered '97.5'	System	06 Aug 2020 23:45:09
	System	06 Aug 2020 23:45:09

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '60db8904-c049-48c1-82bf-87ff24e101b6'	System	06 Aug 2020 23:45:09
User entered 'No (N)'	System	06 Aug 2020 23:45:09

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '60db8904-c049-48c1-82bf-87ff24e101b6'	System	06 Aug 2020 23:45:09
User entered '06 Aug 2020 19:45'	System	06 Aug 2020 23:45:09

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 4'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:39:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6c2135cf-c68a-46eb-9006-814c75841018' User entered 'Yes (Y)'	System	07 Aug 2020 23:40:21
	System	07 Aug 2020 23:40:21

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:39:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6c2135cf-c68a-46eb-9006-814c75841018' User entered '97.6'	System	07 Aug 2020 23:40:21
	System	07 Aug 2020 23:40:21

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6c2135cf-c68a-46eb-9006-814c75841018'	System	07 Aug 2020 23:40:21
User entered 'No (N)'	System	07 Aug 2020 23:40:21

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:20', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6c2135cf-c68a-46eb-9006-814c75841018'	System	07 Aug 2020 23:40:21
User entered '07 Aug 2020 19:40'	System	07 Aug 2020 23:40:21

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 5'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:19:47', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0456073f-e015-4cc1-bc1e-cdc777ec8825'	System	08 Aug 2020 23:20:16
User entered 'Yes (Y)'	System	08 Aug 2020 23:20:16

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:04', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0456073f-e015-4cc1-bc1e-cdc777ec8825' User entered '97.3'	System	08 Aug 2020 23:20:16
	System	08 Aug 2020 23:20:16

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:07', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0456073f-e015-4cc1-bc1e-cdc777ec8825'	System	08 Aug 2020 23:20:16
User entered 'No (N)'	System	08 Aug 2020 23:20:16

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:12', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0456073f-e015-4cc1-bc1e-cdc777ec8825'	System	08 Aug 2020 23:20:16
User entered '08 Aug 2020 19:20'	System	08 Aug 2020 23:20:16

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 6'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:06:34', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '8fd165fe-cf42-42e1-9861-a01d1e6efbb2'	System	09 Aug 2020 23:06:56
User entered 'Yes (Y)'	System	09 Aug 2020 23:06:56

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:06:41', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '8fd165fe-cf42-42e1-9861-a01d1e6efbb2'	System	09 Aug 2020 23:06:56
User entered '98.1'	System	09 Aug 2020 23:06:56

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:06:45', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '8fd165fe-cf42-42e1-9861-a01d1e6efbb2'	System	09 Aug 2020 23:06:56
User entered 'No (N)'	System	09 Aug 2020 23:06:56

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:06:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '8fd165fe-cf42-42e1-9861-a01d1e6efbb2'	System	09 Aug 2020 23:06:56
User entered '09 Aug 2020 19:06'	System	09 Aug 2020 23:06:56

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 7'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:01:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '22920d55-0293-48f0-a960-2380041e319a' User entered 'Yes (Y)'	System	10 Aug 2020 23:01:44
	System	10 Aug 2020 23:01:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:01:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '22920d55-0293-48f0-a960-2380041e319a' User entered '98.3'	System	10 Aug 2020 23:01:44
	System	10 Aug 2020 23:01:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:01:35', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '22920d55-0293-48f0-a960-2380041e319a' User entered 'No (N)'	System	10 Aug 2020 23:01:44
	System	10 Aug 2020 23:01:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:01:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '22920d55-0293-48f0-a960-2380041e319a' User entered '10 Aug 2020 19:01'	System	10 Aug 2020 23:01:44
	System	10 Aug 2020 23:01:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:36:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '296a5857-6b5c-418b-b1a1-e48d575f772a' User entered 'None (1)'	System	04 Aug 2020 20:37:22
	System	04 Aug 2020 20:37:22

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:36:55', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '296a5857-6b5c-418b-b1a1-e48d575f772a' User entered 'No (N)'	System	04 Aug 2020 20:37:22
	System	04 Aug 2020 20:37:22

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:36:59', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '296a5857-6b5c-418b-b1a1-e48d575f772a' User entered 'No (N)'	System	04 Aug 2020 20:37:22
	System	04 Aug 2020 20:37:22

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:37:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '296a5857-6b5c-418b-b1a1-e48d575f772a' User entered 'None (1)'	System	04 Aug 2020 20:37:22
	System	04 Aug 2020 20:37:22

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:37:20', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '296a5857-6b5c-418b-b1a1-e48d575f772a' User entered '04 Aug 2020 16:37'	System	04 Aug 2020 20:37:22
	System	04 Aug 2020 20:37:22

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Aug 2020 16:15'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Aug 2020 18:45'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:29', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '47189bde-c23e-4a46-bbf7-87f20aba16cc' User entered 'None (1)'	System	05 Aug 2020 00:09:51
	System	05 Aug 2020 00:09:51

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:32', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '47189bde-c23e-4a46-bbf7-87f20aba16cc' User entered 'No (N)'	System	05 Aug 2020 00:09:51
	System	05 Aug 2020 00:09:51

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:35', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '47189bde-c23e-4a46-bbf7-87f20aba16cc' User entered 'No (N)'	System	05 Aug 2020 00:09:51
	System	05 Aug 2020 00:09:51

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:39', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '47189bde-c23e-4a46-bbf7-87f20aba16cc' User entered 'None (1)'	System	05 Aug 2020 00:09:51
	System	05 Aug 2020 00:09:51

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:48', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '47189bde-c23e-4a46-bbf7-87f20aba16cc'	System	05 Aug 2020 00:09:51
User entered '04 Aug 2020 20:09'	System	05 Aug 2020 00:09:51

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Aug 2020 19:40'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 2'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:07', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a387c581-a668-4faa-8400-3056073c5b52'	System	05 Aug 2020 23:39:28
User entered 'None (1)'	System	05 Aug 2020 23:39:28

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:11', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a387c581-a668-4faa-8400-3056073c5b52'	System	05 Aug 2020 23:39:28
User entered 'No (N)'	System	05 Aug 2020 23:39:28

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:14', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a387c581-a668-4faa-8400-3056073c5b52'	System	05 Aug 2020 23:39:28
User entered 'No (N)'	System	05 Aug 2020 23:39:28

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a387c581-a668-4faa-8400-3056073c5b52'	System	05 Aug 2020 23:39:28
User entered 'None (1)'	System	05 Aug 2020 23:39:28

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:27', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a387c581-a668-4faa-8400-3056073c5b52'	System	05 Aug 2020 23:39:28
User entered '05 Aug 2020 19:39'	System	05 Aug 2020 23:39:28

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 3'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:19', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '48346898-1727-4798-a44c-0a3e5625fc8d' User entered 'None (1)'	System	06 Aug 2020 23:45:40
	System	06 Aug 2020 23:45:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '48346898-1727-4798-a44c-0a3e5625fc8d' User entered 'No (N)'	System	06 Aug 2020 23:45:40
	System	06 Aug 2020 23:45:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:26', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '48346898-1727-4798-a44c-0a3e5625fc8d' User entered 'No (N)'	System	06 Aug 2020 23:45:40
	System	06 Aug 2020 23:45:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:30', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '48346898-1727-4798-a44c-0a3e5625fc8d' User entered 'None (1)'	System	06 Aug 2020 23:45:40
	System	06 Aug 2020 23:45:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '48346898-1727-4798-a44c-0a3e5625fc8d' User entered '06 Aug 2020 19:45'	System	06 Aug 2020 23:45:40
	System	06 Aug 2020 23:45:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 4'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:37', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a34bc3d-a33e-45b8-80d7-330d06ae6a54'	System	07 Aug 2020 23:41:05
User entered 'Does not interfere with activity (2)'	System	07 Aug 2020 23:41:05

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:40', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a34bc3d-a33e-45b8-80d7-330d06ae6a54' User entered 'No (N)'	System	07 Aug 2020 23:41:05
	System	07 Aug 2020 23:41:05

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:44', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a34bc3d-a33e-45b8-80d7-330d06ae6a54' User entered 'No (N)'	System	07 Aug 2020 23:41:05
	System	07 Aug 2020 23:41:05

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:40:47', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a34bc3d-a33e-45b8-80d7-330d06ae6a54' User entered 'None (1)'	System	07 Aug 2020 23:41:05
	System	07 Aug 2020 23:41:05

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a34bc3d-a33e-45b8-80d7-330d06ae6a54' User entered '07 Aug 2020 19:41'	System	07 Aug 2020 23:41:05
	System	07 Aug 2020 23:41:05

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 5'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:21', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '57fbf54d-b25f-4f0a-81f0-1930a78e45d8'	System	08 Aug 2020 23:20:40
User entered 'None (1)'	System	08 Aug 2020 23:20:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:24', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '57fbf54d-b25f-4f0a-81f0-1930a78e45d8'	System	08 Aug 2020 23:20:40
User entered 'No (N)'	System	08 Aug 2020 23:20:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:27', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '57fbf54d-b25f-4f0a-81f0-1930a78e45d8' User entered 'No (N)'	System	08 Aug 2020 23:20:40
	System	08 Aug 2020 23:20:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '57fbf54d-b25f-4f0a-81f0-1930a78e45d8' User entered 'None (1)'	System	08 Aug 2020 23:20:40
	System	08 Aug 2020 23:20:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '57fbf54d-b25f-4f0a-81f0-1930a78e45d8'	System	08 Aug 2020 23:20:40
User entered '08 Aug 2020 19:20'	System	08 Aug 2020 23:20:40

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 6'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '2f0f9914-17a0-465e-8c72-c89320f92ef9' User entered 'None (1)'	System	09 Aug 2020 23:07:23
	System	09 Aug 2020 23:07:23

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '2f0f9914-17a0-465e-8c72-c89320f92ef9' User entered 'No (N)'	System	09 Aug 2020 23:07:23
	System	09 Aug 2020 23:07:23

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:11', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '2f0f9914-17a0-465e-8c72-c89320f92ef9'	System	09 Aug 2020 23:07:23
User entered 'No (N)'	System	09 Aug 2020 23:07:23

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:15', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '2f0f9914-17a0-465e-8c72-c89320f92ef9' User entered 'None (1)'	System	09 Aug 2020 23:07:23
	System	09 Aug 2020 23:07:23

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '2f0f9914-17a0-465e-8c72-c89320f92ef9' User entered '09 Aug 2020 19:07'	System	09 Aug 2020 23:07:23
	System	09 Aug 2020 23:07:23

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 7'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'be9ceade-3cf2-41ce-9471-1866cdb1dd70' User entered 'None (1)'	System	10 Aug 2020 23:02:37
	System	10 Aug 2020 23:02:37

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:07', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'be9ceade-3cf2-41ce-9471-1866cdb1dd70'	System	10 Aug 2020 23:02:37
User entered 'No (N)'	System	10 Aug 2020 23:02:37

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'be9ceade-3cf2-41ce-9471-1866cdb1dd70' User entered 'No (N)'	System	10 Aug 2020 23:02:37
	System	10 Aug 2020 23:02:37

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'be9ceade-3cf2-41ce-9471-1866cdb1dd70' User entered 'None (1)'	System	10 Aug 2020 23:02:37
	System	10 Aug 2020 23:02:37

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'be9ceade-3cf2-41ce-9471-1866cdb1dd70'	System	10 Aug 2020 23:02:37
User entered '10 Aug 2020 19:02'	System	10 Aug 2020 23:02:37

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:00', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:06', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:14', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:21', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:26', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'None (0)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:37', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered 'No (N)'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T16:38:56', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'e160b832-c22a-4071-8074-e91296033d47'	System	04 Aug 2020 20:38:58
User entered '04 Aug 2020 16:38'	System	04 Aug 2020 20:38:58

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Aug 2020 16:15'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Aug 2020 18:45'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 1, after vaccination (at home)'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:55', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca' User entered 'None (0)'	System	05 Aug 2020 00:10:30
	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:09:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca' User entered 'None (0)'	System	05 Aug 2020 00:10:30
	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca'	System	05 Aug 2020 00:10:30
User entered 'None (0)'	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca' User entered 'None (0)'	System	05 Aug 2020 00:10:30
	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca' User entered 'None (0)'	System	05 Aug 2020 00:10:30
	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:10', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca' User entered 'None (0)'	System	05 Aug 2020 00:10:30
	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:17', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca' User entered 'No (N)'	System	05 Aug 2020 00:10:30
	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-04T20:10:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '85b9eaab-ac5d-48d1-a5af-eb7952a50fca' User entered '04 Aug 2020 20:10'	System	05 Aug 2020 00:10:30
	System	05 Aug 2020 00:10:30

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Aug 2020 19:40'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 2'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'None (0)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:34', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'None (0)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'None (0)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269' User entered 'None (0)'	System	05 Aug 2020 23:40:06
	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:48', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'None (0)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'None (0)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:39:56', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered 'No (N)'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-05T19:40:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'de263414-b988-42ac-aeae-53d084815269'	System	05 Aug 2020 23:40:06
User entered '05 Aug 2020 19:40'	System	05 Aug 2020 23:40:06

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 3'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149' User entered 'None (0)'	System	06 Aug 2020 23:46:20
	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:46', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered 'None (0)'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered 'No interference with activity (1)'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:45:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered 'No interference with activity (1)'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:46:00', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered 'None (0)'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:46:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149' User entered 'None (0)'	System	06 Aug 2020 23:46:20
	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:46:09', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered 'No (N)'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-06T19:46:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'fe611772-066a-4ddb-921f-4851e00d0149'	System	06 Aug 2020 23:46:20
User entered '06 Aug 2020 19:46'	System	06 Aug 2020 23:46:20

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 4'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:09', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f' User entered 'None (0)'	System	07 Aug 2020 23:41:55
	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:16', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f'	System	07 Aug 2020 23:41:55
User entered 'No interference with activity (1)'	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:24', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f'	System	07 Aug 2020 23:41:55
User entered 'No interference with activity (1)'	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f'	System	07 Aug 2020 23:41:55
User entered 'No interference with activity (1)'	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f' User entered 'None (0)'	System	07 Aug 2020 23:41:55
	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:40', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f' User entered 'None (0)'	System	07 Aug 2020 23:41:55
	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:44', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f' User entered 'No (N)'	System	07 Aug 2020 23:41:55
	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-07T19:41:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9a7b8c85-4cf2-46e4-a478-8c4ca76d0c6f' User entered '07 Aug 2020 19:41'	System	07 Aug 2020 23:41:55
	System	07 Aug 2020 23:41:55

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 5'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa' User entered 'None (0)'	System	08 Aug 2020 23:21:11
	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:46', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa' User entered 'None (0)'	System	08 Aug 2020 23:21:11
	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa'	System	08 Aug 2020 23:21:11
User entered 'No interference with activity (1)'	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:52', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa'	System	08 Aug 2020 23:21:11
User entered 'No interference with activity (1)'	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:55', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa' User entered 'None (0)'	System	08 Aug 2020 23:21:11
	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:20:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa' User entered 'None (0)'	System	08 Aug 2020 23:21:11
	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:21:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa'	System	08 Aug 2020 23:21:11
User entered 'No (N)'	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-08T19:21:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9afbbca1-76ab-4a5e-bd41-a0837254b8fa' User entered '08 Aug 2020 19:21'	System	08 Aug 2020 23:21:11
	System	08 Aug 2020 23:21:11

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 6'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:30', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a' User entered 'None (0)'	System	09 Aug 2020 23:08:00
	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a' User entered 'None (0)'	System	09 Aug 2020 23:08:00
	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a' User entered 'None (0)'	System	09 Aug 2020 23:08:00
	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a' User entered 'None (0)'	System	09 Aug 2020 23:08:00
	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:45', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a' User entered 'None (0)'	System	09 Aug 2020 23:08:00
	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:48', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a' User entered 'None (0)'	System	09 Aug 2020 23:08:00
	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:52', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a'	System	09 Aug 2020 23:08:00
User entered 'No (N)'	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-09T19:07:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '0324e71d-ed86-48fd-b3fe-f73a0a702a6a' User entered '09 Aug 2020 19:07'	System	09 Aug 2020 23:08:00
	System	09 Aug 2020 23:08:00

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '10 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 7'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:40', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:02:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc' User entered 'None (0)'	System	10 Aug 2020 23:03:54
	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered 'No interference with activity (1)'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:21', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc' User entered 'None (0)'	System	10 Aug 2020 23:03:54
	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered 'No (N)'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-10T19:03:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1c51eabc-c15c-48d8-a9f3-469ed7251bfc'	System	10 Aug 2020 23:03:54
User entered '10 Aug 2020 19:03'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '10 Aug 2020 12:00'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '11 Aug 2020 11:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 8'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:32:44

Select one response below to indicate the intensity of your **HEADACHE**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:20', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '581af6fe-378f-449f-a1c0-9d2e39227fe7'	System	11 Aug 2020 23:05:28
User entered 'None (0)'	System	11 Aug 2020 23:05:28

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '581af6fe-378f-449f-a1c0-9d2e39227fe7'	System	11 Aug 2020 23:05:28
User entered '11 Aug 2020 19:05'	System	11 Aug 2020 23:05:28

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Headache_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 8'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a99396d-920f-447e-9cb8-92b997d811f9'	System	11 Aug 2020 23:05:15
User entered 'No interference with activity (1)'	System	11 Aug 2020 23:05:15

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '1a99396d-920f-447e-9cb8-92b997d811f9'	System	11 Aug 2020 23:05:15
User entered '11 Aug 2020 19:05'	System	11 Aug 2020 23:05:15

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 9'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

Select one response below to indicate the intensity of your **MUSCLE ACHES ALL OVER BODY**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:11:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd641430a-dfdc-4b5e-b84a-356bf66a7fd8' User entered 'None (0)'	System	12 Aug 2020 23:11:59
	System	12 Aug 2020 23:11:59

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:11:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd641430a-dfdc-4b5e-b84a-356bf66a7fd8'	System	12 Aug 2020 23:11:59
User entered '12 Aug 2020 19:11'	System	12 Aug 2020 23:11:59

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: MuscleAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 8'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9dc84981-3a75-474b-bdd8-60853a462b32'	System	11 Aug 2020 23:05:40
User entered 'No interference with activity (1)'	System	11 Aug 2020 23:05:40

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9dc84981-3a75-474b-bdd8-60853a462b32'	System	11 Aug 2020 23:05:40
User entered '11 Aug 2020 19:05'	System	11 Aug 2020 23:05:40

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 9'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:12:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '7974bd17-75cc-450c-93a9-83f7bbc9ae2c' User entered 'None (0)'	System	12 Aug 2020 23:12:10
	System	12 Aug 2020 23:12:10

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:12:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '7974bd17-75cc-450c-93a9-83f7bbc9ae2c'	System	12 Aug 2020 23:12:10
User entered '12 Aug 2020 19:12'	System	12 Aug 2020 23:12:10

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 8'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:32:44

Select one response below to indicate the level of your **NAUSEA/VOMITING**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:43', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'eb55d0c4-d181-4429-be96-35c922f1f804'	System	11 Aug 2020 23:05:50
User entered 'None (0)'	System	11 Aug 2020 23:05:50

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'eb55d0c4-d181-4429-be96-35c922f1f804'	System	11 Aug 2020 23:05:50
User entered '11 Aug 2020 19:05'	System	11 Aug 2020 23:05:50

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Nausea_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 8'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:54', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '7c595b39-3d16-4959-8d24-a4548f0d9c20'	System	11 Aug 2020 23:06:01
User entered 'No (N)'	System	11 Aug 2020 23:06:01

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-11T19:05:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '7c595b39-3d16-4959-8d24-a4548f0d9c20'	System	11 Aug 2020 23:06:01
User entered '11 Aug 2020 19:05'	System	11 Aug 2020 23:06:01

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '11 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '12 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	10 Aug 2020 23:03:54
User entered 'Day 9'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:12:15', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6e4d40ff-34b1-40ed-aba5-bbb0c8486cce'	System	12 Aug 2020 23:12:21
User entered 'No (N)'	System	12 Aug 2020 23:12:21

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-08-12T19:12:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '6e4d40ff-34b1-40ed-aba5-bbb0c8486cce'	System	12 Aug 2020 23:12:21
User entered '12 Aug 2020 19:12'	System	12 Aug 2020 23:12:21

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '12 Aug 2020 12:00'	System	10 Aug 2020 23:03:54

US3412125

Folder: Diary Dose 1 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '13 Aug 2020 11:59'	System	10 Aug 2020 23:03:54

US3412125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	12 Aug 2020 20:03:51

US3412125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '12 Aug 2020'	Steven Anderson (b) (4)	12 Aug 2020 20:03:51

US3412125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	12 Aug 2020 20:03:51

US3412125

Folder: Safety Call Day 8 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	12 Aug 2020 20:03:51

US3412125

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	12 Aug 2020 20:04:32

US3412125

Folder: Safety Call Day 8 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'I'	System	12 Aug 2020 20:04:32

US3412125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 00:07:08
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	19 Aug 2020 23:14:29

US3412125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:07:08
User entered '19 Aug 2020'	Steven Anderson (b) (4)	19 Aug 2020 23:14:29

US3412125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 00:07:08
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4) (b) (4)	19 Aug 2020 23:14:29

US3412125

Folder: Safety Call Day 15 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 00:07:08
User entered empty.	Steven Anderson (b) (4) (b) (4)	19 Aug 2020 23:14:29

US3412125

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 00:06:47
User entered 'Yes (Y)'	Steven Anderson (b) (4) (b) (4)	19 Aug 2020 23:14:34

US3412125

Folder: Safety Call Day 15 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	04 Apr 2021 17:13:01
User entered 'I'	System	19 Aug 2020 23:14:34

US3412125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:23:10

US3412125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered '25 Aug 2020'	Steven Anderson (b) (4)	01 Sep 2020 16:23:10

US3412125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Contact Made (CONTACT MADE)'	Steven Anderson (b) (4)	01 Sep 2020 16:23:10

US3412125

Folder: Safety Call Day 22 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:23:10

US3412125

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:23:15

US3412125

Folder: Safety Call Day 22 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 15:14:23
User entered 'I'	System	01 Sep 2020 16:23:15

US3412125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:25:11

US3412125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '01 Sep 2020'	Steven Anderson (b) (4)	01 Sep 2020 16:25:11

US3412125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Clinic (Clinic)'	Steven Anderson (b) (4)	01 Sep 2020 16:25:11

US3412125

Folder: Visit 2 Day 29 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'VISIT2'	System	01 Sep 2020 16:25:11

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User accepted default value 'Pre-Dose (PREDOSE)'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '01 Sep 2020'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '12:00'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered '01 Sep 2020 12:00'	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '36.8' C	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Oral (Oral)'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '60'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'bpm'	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '16'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'breaths/min'	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '110'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'mmHg'	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '64'	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (1)

Generated On: 09 Jun 2021 17:32:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'mmHg'	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Timepoint](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User accepted default value 'Post-Dose (POSTDOSE)'	Steven Anderson (b) (4) (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

Were vital signs assessed?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	16 Sep 2020 18:52:43
User entered 'Yes (Y)' reason for change: Data Entry Error	System	16 Sep 2020 18:52:43
User opened query 'Data is required. Please complete.' (Site from System).	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	(b) (4)	
	System	01 Sep 2020 16:26:12
	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '01 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '13:25' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered '01 Sep 2020 13:25'	System	16 Sep 2020 18:52:43
User entered empty.	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

Temperature (xxx.x)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '97.1' F reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Route of measurement](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Oral (Oral)' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[If Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '62' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Pulse units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'bpm'	System	16 Sep 2020 18:52:43
User entered empty.	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '12' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	(b) (4)	
	Steven Anderson (b) (4)	01 Sep 2020 16:26:12
	(b) (4)	

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'breaths/min'	System	16 Sep 2020 18:52:43
User entered empty.	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '130' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'mmHg'	System	16 Sep 2020 18:52:43
User entered empty.	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '68' reason for change: Data Entry Error	Steven Anderson (b) (4)	16 Sep 2020 18:52:43
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Vital Signs - Dosing (2)

Generated On: 09 Jun 2021 17:32:44

Diastolic Blood Pressure units

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'mmHg'	System	16 Sep 2020 18:52:43
User entered empty.	System	01 Sep 2020 16:26:12

US3412125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:32:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:26:31

US3412125

Folder: Visit 2 Day 29 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:32:44

Date of examination (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '01 Sep 2020'	Steven Anderson (b) (4)	01 Sep 2020 16:26:31

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[Was study treatment given?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[If No, reason not given](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

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)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[What was the study treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'MRNA-1273 OR PLACEBO'	System	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

What was the treatment date? (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '01 Sep 2020'	Steven Anderson (b) (4)	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[What was the treatment time? \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '12:55'	Steven Anderson (b) (4)	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[Treatment Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered '01 Sep 2020 12:55'	System	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[Which arm was used to give treatment?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Left Arm (LEFT ARM)'	Steven Anderson (b) (4)	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

[What was the frequency of the study treatment dosing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'ONCE'	System	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Exposure

Generated On: 09 Jun 2021 17:32:44

What was the route of administration for the study treatment?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'INTRAMUSCULAR'	System	01 Sep 2020 16:42:41

US3412125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:27:32

US3412125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '01 Sep 2020'	Steven Anderson (b) (4)	01 Sep 2020 16:27:32

US3412125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '12:08'	Steven Anderson (b) (4)	01 Sep 2020 16:27:32

US3412125

Folder: Visit 2 Day 29 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered '01 Sep 2020 12:08'	System	01 Sep 2020 16:27:32

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab

Generated On: 09 Jun 2021 17:32:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '01 Sep 2020'	Steven Anderson (b) (4)	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:32:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User accepted default value 'Nasopharyngeal Swab 1 (NASAL1)'	Steven Anderson (b) (4)	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:32:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:32:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered '12:12'	Steven Anderson (b) (4)	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (1)

Generated On: 09 Jun 2021 17:32:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered '01 Sep 2020 12:12'	System	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:32:44

[Lab Test](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User accepted default value 'Nasopharyngeal Swab 2 (NASAL2)'	Steven Anderson (b) (4)	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:32:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'No (N)'	Steven Anderson (b) (4)	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:32:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered empty.	Steven Anderson (b) (4)	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Central Laboratory - Nasopharyngeal Swab (2)

Generated On: 09 Jun 2021 17:32:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered empty.	System	01 Sep 2020 16:27:52

US3412125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 02:37:27
User entered 'Yes (Y)'	Steven Anderson (b) (4)	01 Sep 2020 16:27:58

US3412125

Folder: Visit 2 Day 29 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 11:05:33
User entered 'I'	System	01 Sep 2020 16:27:58

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:29:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '004b445d-8163-45bb-8b7a-d033f9ca6be9' User entered 'Yes (Y)'	System	01 Sep 2020 17:30:17
	System	01 Sep 2020 17:30:17

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:29:41', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '004b445d-8163-45bb-8b7a-d033f9ca6be9' User entered '97.1'	System	01 Sep 2020 17:30:17
	System	01 Sep 2020 17:30:17

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '004b445d-8163-45bb-8b7a-d033f9ca6be9' User entered 'No (N)'	System	01 Sep 2020 17:30:17
	System	01 Sep 2020 17:30:17

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '004b445d-8163-45bb-8b7a-d033f9ca6be9'	System	01 Sep 2020 17:30:17
User entered '01 Sep 2020 13:30'	System	01 Sep 2020 17:30:17

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '01 Sep 2020 13:15'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '01 Sep 2020 15:45'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:15', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '3ca70747-a2d3-4e8f-90e1-a72d5a5fe5af' User entered 'Yes (Y)'	System	01 Sep 2020 23:06:40
	System	01 Sep 2020 23:06:40

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '3ca70747-a2d3-4e8f-90e1-a72d5a5fe5af' User entered '97.3'	System	01 Sep 2020 23:06:40
	System	01 Sep 2020 23:06:40

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:30', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '3ca70747-a2d3-4e8f-90e1-a72d5a5fe5af' User entered 'No (N)'	System	01 Sep 2020 23:06:40
	System	01 Sep 2020 23:06:40

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '3ca70747-a2d3-4e8f-90e1-a72d5a5fe5af' User entered '01 Sep 2020 19:06'	System	01 Sep 2020 23:06:40
	System	01 Sep 2020 23:06:40

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '01 Sep 2020 16:40'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 2'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '37de59e5-b47e-4a17-b1e5-5b7bbec5d42b' User entered 'Yes (Y)'	System	02 Sep 2020 23:53:32
	System	02 Sep 2020 23:53:32

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '37de59e5-b47e-4a17-b1e5-5b7bbec5d42b' User entered '97.1'	System	02 Sep 2020 23:53:32
	System	02 Sep 2020 23:53:32

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:17', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '37de59e5-b47e-4a17-b1e5-5b7bbec5d42b' User entered 'No (N)'	System	02 Sep 2020 23:53:32
	System	02 Sep 2020 23:53:32

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '37de59e5-b47e-4a17-b1e5-5b7bbec5d42b' User entered '02 Sep 2020 19:53'	System	02 Sep 2020 23:53:32
	System	02 Sep 2020 23:53:32

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 3'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:43:50', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '11800d38-e4ae-4a40-a555-873941348ab6' User entered 'Yes (Y)'	System	04 Sep 2020 00:44:11
	System	04 Sep 2020 00:44:11

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:43:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '11800d38-e4ae-4a40-a555-873941348ab6'	System	04 Sep 2020 00:44:11
User entered '96.8'	System	04 Sep 2020 00:44:11

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:01', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '11800d38-e4ae-4a40-a555-873941348ab6'	System	04 Sep 2020 00:44:11
User entered 'No (N)'	System	04 Sep 2020 00:44:11

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:09', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '11800d38-e4ae-4a40-a555-873941348ab6'	System	04 Sep 2020 00:44:11
User entered '03 Sep 2020 20:44'	System	04 Sep 2020 00:44:11

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 4'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:02:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796'	System	04 Sep 2020 23:04:09
User entered 'Yes (Y)'	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:03:27', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796' User entered '97.3'	System	04 Sep 2020 23:04:09
	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:03:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796' User entered 'Yes (Y)'	System	04 Sep 2020 23:04:09
	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
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 'CONTACTED' (Site from System).	(b) (4), (b) (6)	14 Oct 2020 10:00:39
User opened query 'Per the participant response, medication was taken to treat pain or fever. Please confirm the participant was contacted to determine the medication details and record on the concomitant medication pages. Thank you.' (Site from System).	Mylene Asmar-Rios	02 Oct 2020 17:15:52
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:03:52', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796'	(b) (4)	
User entered '1'	System	04 Sep 2020 23:04:09
	System	04 Sep 2020 23:04:09
	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

To **PREVENT** pain or fever from occurring

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:03:52', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796' User entered '0'	System	04 Sep 2020 23:04:09
	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:04:06', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'a0904688-be1a-475c-854a-a56addb0e796'	System	04 Sep 2020 23:04:09
User entered '04 Sep 2020 19:04'	System	04 Sep 2020 23:04:09

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 5'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:42:20', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd2b1c41d-b82a-4d81-a0ea-eccde9726715' User entered 'Yes (Y)'	System	05 Sep 2020 23:42:44
	System	05 Sep 2020 23:42:44

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:42:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd2b1c41d-b82a-4d81-a0ea-eccde9726715' User entered '95.7'	System	05 Sep 2020 23:42:44
	System	05 Sep 2020 23:42:44

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:42:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd2b1c41d-b82a-4d81-a0ea-eccde9726715' User entered 'No (N)'	System	05 Sep 2020 23:42:44
	System	05 Sep 2020 23:42:44

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:42:42', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd2b1c41d-b82a-4d81-a0ea-eccde9726715' User entered '05 Sep 2020 19:42'	System	05 Sep 2020 23:42:44
	System	05 Sep 2020 23:42:44

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 6'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:55:52', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd430823e-ddd0-4ee0-bf03-ffaf9eff6e0f' User entered 'Yes (Y)'	System	06 Sep 2020 23:56:10
	System	06 Sep 2020 23:56:10

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:55:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd430823e-ddd0-4ee0-bf03-ffaf9eff6e0f' User entered '97.0'	System	06 Sep 2020 23:56:10
	System	06 Sep 2020 23:56:10

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd430823e-ddd0-4ee0-bf03-ffaf9eff6e0f'	System	06 Sep 2020 23:56:10
User entered 'No (N)'	System	06 Sep 2020 23:56:10

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'd430823e-ddd0-4ee0-bf03-ffaf9eff6e0f'	System	06 Sep 2020 23:56:10
User entered '06 Sep 2020 19:56'	System	06 Sep 2020 23:56:10

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 7'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

Was **TEMPERATURE** taken?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:35:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f18ab851-292c-4d86-92e1-701ae1a1204b' User entered 'Yes (Y)'	System	07 Sep 2020 23:36:27
	System	07 Sep 2020 23:36:27

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

Please record your **TEMPERATURE** in °F

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:36:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f18ab851-292c-4d86-92e1-701ae1a1204b' User entered '98.0'	System	07 Sep 2020 23:36:27
	System	07 Sep 2020 23:36:27

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:36:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f18ab851-292c-4d86-92e1-701ae1a1204b' User entered 'No (N)'	System	07 Sep 2020 23:36:27
	System	07 Sep 2020 23:36:27

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:36:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f18ab851-292c-4d86-92e1-701ae1a1204b' User entered '07 Sep 2020 19:36'	System	07 Sep 2020 23:36:27
	System	07 Sep 2020 23:36:27

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Temperature_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:26', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f0f3024b-72fb-450d-acc4-1c2627ad1b38'	System	01 Sep 2020 17:30:56
User entered 'Any use of prescription pain reliever or System prevents daily activity (4)'		01 Sep 2020 17:30:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:30', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f0f3024b-72fb-450d-acc4-1c2627ad1b38' User entered 'No (N)'	System	01 Sep 2020 17:30:56
	System	01 Sep 2020 17:30:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f0f3024b-72fb-450d-acc4-1c2627ad1b38' User entered 'No (N)'	System	01 Sep 2020 17:30:56
	System	01 Sep 2020 17:30:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:39', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f0f3024b-72fb-450d-acc4-1c2627ad1b38' User entered 'None (1)'	System	01 Sep 2020 17:30:56
	System	01 Sep 2020 17:30:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:30:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f0f3024b-72fb-450d-acc4-1c2627ad1b38'	System	01 Sep 2020 17:30:56
User entered '01 Sep 2020 13:30'	System	01 Sep 2020 17:30:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '01 Sep 2020 13:15'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '01 Sep 2020 15:45'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'ba0719bb-ab44-4aba-8a57-642cbef4fed5' User entered 'None (1)'	System	01 Sep 2020 23:07:18
	System	01 Sep 2020 23:07:18

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'ba0719bb-ab44-4aba-8a57-642cbef4fed5' User entered 'No (N)'	System	01 Sep 2020 23:07:18
	System	01 Sep 2020 23:07:18

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:06:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'ba0719bb-ab44-4aba-8a57-642cbef4fed5' User entered 'No (N)'	System	01 Sep 2020 23:07:18
	System	01 Sep 2020 23:07:18

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:04', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'ba0719bb-ab44-4aba-8a57-642cbef4fed5' User entered 'None (1)'	System	01 Sep 2020 23:07:18
	System	01 Sep 2020 23:07:18

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:16', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'ba0719bb-ab44-4aba-8a57-642cbef4fed5'	System	01 Sep 2020 23:07:18
User entered '01 Sep 2020 19:07'	System	01 Sep 2020 23:07:18

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '01 Sep 2020 16:40'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 2'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:55', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '79c5cb8f-985a-4b6e-8fff-e1d7a785deca'	System	02 Sep 2020 23:54:30
User entered 'Repeated use of over-the-counter pain reliever > 24 hours or interferes with activity (3)'	System	02 Sep 2020 23:54:30

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:53:59', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '79c5cb8f-985a-4b6e-8fff-e1d7a785deca' User entered 'No (N)'	System	02 Sep 2020 23:54:30
	System	02 Sep 2020 23:54:30

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '79c5cb8f-985a-4b6e-8fff-e1d7a785deca' User entered 'No (N)'	System	02 Sep 2020 23:54:30
	System	02 Sep 2020 23:54:30

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:10', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '79c5cb8f-985a-4b6e-8fff-e1d7a785deca' User entered 'None (1)'	System	02 Sep 2020 23:54:30
	System	02 Sep 2020 23:54:30

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '79c5cb8f-985a-4b6e-8fff-e1d7a785deca'	System	02 Sep 2020 23:54:30
User entered '02 Sep 2020 19:54'	System	02 Sep 2020 23:54:30

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 3'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:21', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9d8b5ef2-ae2f-4804-aab0-e061f231972c' User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 00:44:49
	System	04 Sep 2020 00:44:49

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:24', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9d8b5ef2-ae2f-4804-aab0-e061f231972c' User entered 'No (N)'	System	04 Sep 2020 00:44:49
	System	04 Sep 2020 00:44:49

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9d8b5ef2-ae2f-4804-aab0-e061f231972c' User entered 'No (N)'	System	04 Sep 2020 00:44:49
	System	04 Sep 2020 00:44:49

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:35', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9d8b5ef2-ae2f-4804-aab0-e061f231972c' User entered 'None (1)'	System	04 Sep 2020 00:44:49
	System	04 Sep 2020 00:44:49

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:46', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9d8b5ef2-ae2f-4804-aab0-e061f231972c' User entered '03 Sep 2020 20:44'	System	04 Sep 2020 00:44:49
	System	04 Sep 2020 00:44:49

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 4'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:29', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '32d9dad9-89ba-45b1-98dc-94be292b1075'	System	04 Sep 2020 23:05:56
User entered 'Does not interfere with activity (2)'	System	04 Sep 2020 23:05:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:32', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '32d9dad9-89ba-45b1-98dc-94be292b1075'	System	04 Sep 2020 23:05:56
User entered 'No (N)'	System	04 Sep 2020 23:05:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:37', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '32d9dad9-89ba-45b1-98dc-94be292b1075'	System	04 Sep 2020 23:05:56
User entered 'No (N)'	System	04 Sep 2020 23:05:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:42', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '32d9dad9-89ba-45b1-98dc-94be292b1075'	System	04 Sep 2020 23:05:56
User entered 'None (1)'	System	04 Sep 2020 23:05:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '32d9dad9-89ba-45b1-98dc-94be292b1075'	System	04 Sep 2020 23:05:56
User entered '04 Sep 2020 19:05'	System	04 Sep 2020 23:05:56

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 5'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:42:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '948309c5-f6ad-4f3a-8a9b-613aa2bc732b'	System	05 Sep 2020 23:43:32
User entered 'Does not interfere with activity (2)'	System	05 Sep 2020 23:43:32

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '948309c5-f6ad-4f3a-8a9b-613aa2bc732b' User entered 'No (N)'	System	05 Sep 2020 23:43:32
	System	05 Sep 2020 23:43:32

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:06', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '948309c5-f6ad-4f3a-8a9b-613aa2bc732b'	System	05 Sep 2020 23:43:32
User entered 'No (N)'	System	05 Sep 2020 23:43:32

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '948309c5-f6ad-4f3a-8a9b-613aa2bc732b' User entered 'None (1)'	System	05 Sep 2020 23:43:32
	System	05 Sep 2020 23:43:32

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:27', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '948309c5-f6ad-4f3a-8a9b-613aa2bc732b' User entered '05 Sep 2020 19:43'	System	05 Sep 2020 23:43:32
	System	05 Sep 2020 23:43:32

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 6'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '97508007-102c-4781-afaf-234ce81fdb12'	System	06 Sep 2020 23:57:04
User entered 'Does not interfere with activity (2)'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

Is there any REDNESS AT INJECTION SITE?

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '97508007-102c-4781-afaf-234ce81fdb12'	System	06 Sep 2020 23:57:04
User entered 'No (N)'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:34', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '97508007-102c-4781-afaf-234ce81fdb12'	System	06 Sep 2020 23:57:04
User entered 'No (N)'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:56:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '97508007-102c-4781-afaf-234ce81fdb12'	System	06 Sep 2020 23:57:04
User entered 'None (1)'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '97508007-102c-4781-afaf-234ce81fdb12'	System	06 Sep 2020 23:57:04
User entered '06 Sep 2020 19:57'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 7'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:37:42', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'cc450744-1ba5-433d-8aff-4ea80f9f1122'	System	07 Sep 2020 23:38:09
User entered 'Does not interfere with activity (2)'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:36:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'cc450744-1ba5-433d-8aff-4ea80f9f1122'	System	07 Sep 2020 23:38:09
User entered 'No (N)'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:36:56', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'cc450744-1ba5-433d-8aff-4ea80f9f1122'	System	07 Sep 2020 23:38:09
User entered 'No (N)'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:37:05', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'cc450744-1ba5-433d-8aff-4ea80f9f1122'	System	07 Sep 2020 23:38:09
User entered 'None (1)'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:08', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'cc450744-1ba5-433d-8aff-4ea80f9f1122'	System	07 Sep 2020 23:38:09
User entered '07 Sep 2020 19:38'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Site_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, 30 Minutes after vaccination (at study clinic)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:00', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6' User entered 'None (0)'	System	01 Sep 2020 17:31:35
	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6' User entered 'None (0)'	System	01 Sep 2020 17:31:35
	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:06', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6' User entered 'None (0)'	System	01 Sep 2020 17:31:35
	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:10', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6' User entered 'None (0)'	System	01 Sep 2020 17:31:35
	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:13', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6' User entered 'None (0)'	System	01 Sep 2020 17:31:35
	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:17', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6'	System	01 Sep 2020 17:31:35
User entered 'None (0)'	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6' User entered 'No (N)'	System	01 Sep 2020 17:31:35
	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T13:31:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c651bf23-198c-4946-9184-6eab8eefaba6'	System	01 Sep 2020 17:31:35
User entered '01 Sep 2020 13:31'	System	01 Sep 2020 17:31:35

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '01 Sep 2020 13:15'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/1)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '01 Sep 2020 15:45'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 1, after vaccination (at home)'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:21', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a' User entered 'None (0)'	System	01 Sep 2020 23:07:55
	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a' User entered 'None (0)'	System	01 Sep 2020 23:07:55
	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:28', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a' User entered 'None (0)'	System	01 Sep 2020 23:07:55
	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a' User entered 'None (0)'	System	01 Sep 2020 23:07:55
	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:34', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a' User entered 'None (0)'	System	01 Sep 2020 23:07:55
	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:37', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a' User entered 'None (0)'	System	01 Sep 2020 23:07:55
	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:41', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a' User entered 'No (N)'	System	01 Sep 2020 23:07:55
	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-01T19:07:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'def8e474-a54c-4c09-986f-57cb7087889a' User entered '01 Sep 2020 19:07'	System	01 Sep 2020 23:07:55
	System	01 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '01 Sep 2020 16:40'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(1/2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '02 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 2'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'No interference with activity (1)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:55:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'None (0)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'No interference with activity (1)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:54:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'None (0)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:55:38', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'No interference with activity or 1-2 episodes/24 hours (1)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:55:07', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'No interference with activity (1)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:56:19', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered 'No (N)'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-02T19:56:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'c54e6380-dffc-4ffa-8a5e-2391be6fae6c'	System	02 Sep 2020 23:56:40
User entered '02 Sep 2020 19:56'	System	02 Sep 2020 23:56:40

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '02 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(2)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '03 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 3'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:54', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44' User entered 'None (0)'	System	04 Sep 2020 00:45:27
	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:44:56', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44' User entered 'None (0)'	System	04 Sep 2020 00:45:27
	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:00', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered 'No interference with activity (1)'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:04', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered 'No interference with activity (1)'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:07', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44' User entered 'None (0)'	System	04 Sep 2020 00:45:27
	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:10', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44' User entered 'None (0)'	System	04 Sep 2020 00:45:27
	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:14', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered 'No (N)'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-03T20:45:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '5fc0435a-c7a0-4d6d-bd56-c662ca6c9d44'	System	04 Sep 2020 00:45:27
User entered '03 Sep 2020 20:45'	System	04 Sep 2020 00:45:27

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '03 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(3)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 4'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:05:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56' User entered 'None (0)'	System	04 Sep 2020 23:07:55
	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:06:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56' User entered 'None (0)'	System	04 Sep 2020 23:07:55
	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:06:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56'	System	04 Sep 2020 23:07:55
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:07:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56'	System	04 Sep 2020 23:07:55
User entered 'No interference with activity (1)'	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:06:39', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56' User entered 'None (0)'	System	04 Sep 2020 23:07:55
	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:07:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56' User entered 'None (0)'	System	04 Sep 2020 23:07:55
	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:06:47', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56' User entered 'No (N)'	System	04 Sep 2020 23:07:55
	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-04T19:07:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '4311d550-9176-4332-b2f3-e223085e7a56'	System	04 Sep 2020 23:07:55
User entered '04 Sep 2020 19:07'	System	04 Sep 2020 23:07:55

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '04 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(4)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 5'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:32', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae' User entered 'None (0)'	System	05 Sep 2020 23:44:04
	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:35', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae' User entered 'None (0)'	System	05 Sep 2020 23:44:04
	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:40', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae' User entered 'None (0)'	System	05 Sep 2020 23:44:04
	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:44', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae'	System	05 Sep 2020 23:44:04
User entered 'No interference with activity (1)'	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:47', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae' User entered 'None (0)'	System	05 Sep 2020 23:44:04
	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae' User entered 'None (0)'	System	05 Sep 2020 23:44:04
	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:43:53', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae'	System	05 Sep 2020 23:44:04
User entered 'No (N)'	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-05T19:44:02', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9967855b-070e-4e97-8fb7-e3a11a0fb1ae' User entered '05 Sep 2020 19:44'	System	05 Sep 2020 23:44:04
	System	05 Sep 2020 23:44:04

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '05 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(5)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 6'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:20', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'No interference with activity (1)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'None (0)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:27', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'None (0)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:31', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'No interference with activity (1)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:33', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'None (0)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac' User entered 'None (0)'	System	06 Sep 2020 23:57:52
	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:39', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered 'No (N)'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-06T19:57:51', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: 'f97b2de2-7753-498b-a5a6-809cf2e7ceac'	System	06 Sep 2020 23:57:52
User entered '06 Sep 2020 19:57'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '06 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(6)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	01 Sep 2020 16:42:41
User entered 'Day 7'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

HEADACHE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:18', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'None (0)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

FATIGUE

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:29', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943' User entered 'None (0)'	System	07 Sep 2020 23:39:29
	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

MUSCLE ACHES ALL OVER BODY

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:35', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943' User entered 'None (0)'	System	07 Sep 2020 23:39:29
	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

JOINT ACHES IN SEVERAL JOINTS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:50', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'No interference with activity (1)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

NAUSEA/VOMITING

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:54', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'None (0)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

CHILLS

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:38:58', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'None (0)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:39:10', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered 'No (N)'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-09-07T19:39:25', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '874c1e94-f821-4386-876c-fc29d8c0c943'	System	07 Sep 2020 23:39:29
User entered '07 Sep 2020 19:39'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '07 Sep 2020 12:00'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: General_Day(7)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Sep 2020 11:59'	System	01 Sep 2020 16:42:41

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	06 Sep 2020 23:57:04
User entered 'Day 8'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	07 Sep 2020 23:38:09
User entered 'Day 9'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 17:32:44

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

Please select one response below

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Time Stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Injection Pain_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	06 Sep 2020 23:57:52
User entered 'Day 8'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 23:57:52

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	07 Sep 2020 23:39:29
User entered 'Day 9'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

Select one response below to indicate the intensity of your **JOINT ACHES IN SEVERAL JOINTS**

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: JointsAche_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:39:29

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	06 Sep 2020 23:57:04
User entered 'Day 8'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '08 Sep 2020 12:00'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(8)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Sep 2020 11:59'	System	06 Sep 2020 23:57:04

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	07 Sep 2020 23:38:09
User entered 'Day 9'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Time stamp](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '09 Sep 2020 12:00'	System	07 Sep 2020 23:38:09

US3412125

Folder: Diary Dose 2 (1)

Form: Medical Attention_Day(9)

Generated On: 09 Jun 2021 17:32:44

[PC Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
User entered '10 Sep 2020 11:59'	System	07 Sep 2020 23:38:09

US3412125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:59:57

US3412125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User closed query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22Jan2021 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)	12 Feb 2021 19:49:05
User closed query 'Per GCL Lab Reconciliation: Swab: Sample dated 22-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).		12 Feb 2021 19:49:03
Query 'Per GCL Lab Reconciliation: Antibody-mediated Immunogenicity: Sample dated 22Jan2021 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)	12 Feb 2021 13:24:25
Query 'Per GCL Lab Reconciliation: Swab: Sample dated 22-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)	12 Feb 2021 13:24:14

US3412125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

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 22Jan2021 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 16:04:48
User opened query 'Per GCL Lab Reconciliation: Swab: Sample dated 22-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 10:05:24
User entered '08 Sep 2020'		08 Sep 2020 20:59:57

US3412125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Contact Made (CONTACT MADE)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:59:57

US3412125

Folder: Safety Call Day 36 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered empty.	(b) (4) (b) (4), (b) (6)	08 Sep 2020 20:59:57

US3412125

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User signature succeeded.	Richard Powell (b) (4)	13 Feb 2021 04:49:09
User entered 'Yes (Y)'	(b) (4) (b) (4), (b) (6)	08 Sep 2020 21:00:05

US3412125

Folder: Safety Call Day 36 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User entered 'I'	System	08 Sep 2020 21:00:05

US3412125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'Yes (Y)'	(b) (4)	29 Mar 2021 12:18:25
	Andrea Newlands (b) (4)	
	(b) (4)	

US3412125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

Date of Contact or Contact Attempt (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered '15 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	29 Mar 2021 12:18:40
User closed query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	(b) (4)	
	System	29 Mar 2021 12:18:28
Query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' answered by data change (Site from System).	System	29 Mar 2021 12:18:28
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	29 Mar 2021 12:18:28
User entered '16 Sep 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:18:28
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	29 Mar 2021 12:18:25
User opened query 'Safety Call Day 43 'Date of Contact or Contact Attempt' is less than 14 days or greater than 17 days after Visit 2 Treatment Date on the Exposure Form. Please review and reconcile, or clarify.' (Site from System).	System	29 Mar 2021 12:18:25
User entered '16 Sep 2021'	Andrea Newlands (b) (4)	29 Mar 2021 12:18:25
	(b) (4)	

US3412125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'Contact Not Made (CONTACT NOT MADE)'	Andrea Newlands (b) (4)	29 Mar 2021 12:18:25

US3412125

Folder: Safety Call Day 43 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'SUBJECT WAS IN A SERIOUS MOTOR VEHICLE ACCIDENT ON 08AUG2020 AND WAS HOSPITALIZED. SITE REACHED OUT TO SUBJECT AS WELL AS SUBJECT'S SPOUSE BUT WAS NOT ABLE TO MAKE CONTACT.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:29:52
User entered 'SUBJECT WAS IN A SERIOUS MOTOR VEHICLE ACCIDENT ON 08AUG2020 AND WAS HOSPITALIZED. SITE REACHED OUT TO SUBJECT AS WELL AS SUBJECT'S SPOUSE BUT WERE NOT ABLE TO MAKE CONTACT.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:29:43
User closed query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	29 Mar 2021 12:22:30
Please review and reconcile.' (Site from System).		
User entered 'subject was in a serious motor vehicle accident on 08aug2020 and was hospitalized. Site reached out to subject as well as subject's husband but were not able to make contact.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:22:30
User opened query 'The Contact Status is 'CONTACT NOT MADE'; however, Comments have not been provided.	System	29 Mar 2021 12:18:25
Please review and reconcile.' (Site from System).		
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:18:25

US3412125

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 12:22:35

US3412125

Folder: Safety Call Day 43 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 18:38:07
User entered 'I'	System	29 Mar 2021 12:22:35

US3412125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 12:25:18
	(b) (4)	

US3412125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:18
	(b) (4)	

US3412125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:18
	(b) (4)	

US3412125

Folder: Safety Call Day 50 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
User entered 'subject was in a motor vehicle accident on 08Aug2020. Since notifying the site the date after, subject has not been reachable and has not reached out.'	(b) (4) Andrea Newlands (b) (4)	29 Mar 2021 12:25:18

US3412125

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 12:25:22
	(b) (4)	

US3412125

Folder: Safety Call Day 50 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 12:25:22

US3412125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 12:25:48
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:48
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

Was visit performed at the participant's home or at the clinic?

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:48
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT3'	System	29 Mar 2021 12:25:48

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 12:25:54
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:54
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:54
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 12:25:54

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:54
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:54
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:54
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:54
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 12:25:54

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:54
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 12:25:54

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:54
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 12:25:54

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:25:54
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 12:25:54

US3412125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:32:44

[Was the physical examination performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 12:26:13
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:32:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:26:13
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 12:26:17
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:26:17
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:26:17
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	29 Mar 2021 12:26:17

US3412125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:26:37
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 12:26:22
	(b) (4)	

US3412125

Folder: Visit 3 Day 57 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 12:26:37
User entered empty.	System	29 Mar 2021 12:26:22

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 64'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:01:49', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-aebc-4ca8-98c9-ae33d0477f47'	System	07 Oct 2020 22:02:46
User entered 'Yes (Y)'	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:01:57', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-aebc-4ca8-98c9-ae33d0477f47'	System	07 Oct 2020 22:02:46
User entered 'No (N)'	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:02:03', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-aebc-4ca8-98c9-ae33d0477f47'	System	07 Oct 2020 22:02:46
User entered 'No (N)'	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

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 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:02:11', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-aebc-4ca8-98c9-ae33d0477f47'	System	07 Oct 2020 22:02:46
User entered 'Yes (Y)'	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:02:22', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-aebc-4ca8-98c9-ae33d0477f47'	System	07 Oct 2020 22:02:46
User entered 'I confirm I have read this message and will call the study clinic immediately (9)'	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
External Audit Record. Reason for change: 'Not Provided', Location OID: 'ePRODevice (55BA1FF2-D2DE-4BC8-8A5D-096F5C1CA3D5)', Time: '2020-10-07T18:02:36', User OID: 'PatientReportedOutcome (US3412125)', ODM File OID: '9bf9a1bc-aebc-4ca8-98c9-ae33d0477f47' User entered '07 Oct 2020 18:02:36'	System	07 Oct 2020 22:02:46
	System	07 Oct 2020 22:02:46

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '04 Oct 2020 00:01'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	25 Feb 2021 10:09:43
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '08 Oct 2020 23:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 71'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Have you been exposed to someone with 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '11 Oct 2020 00:01'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '15 Oct 2020 23:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 78'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Have you been exposed to someone with 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '18 Oct 2020 00:01'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '22 Oct 2020 23:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 92'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Have you been exposed to someone with 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '01 Nov 2020 00:01'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '05 Nov 2020 23:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 99'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Have you been exposed to someone with 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

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[Date and time of submission](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '08 Nov 2020 00:01'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '12 Nov 2020 23:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered 'Day 106'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Have you been exposed to someone with 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

Fever (Temperature \geq 100.4°F/38°C)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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[Chills](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:32:44

[Cough](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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[Shortness of breath](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Difficulty breathing](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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[Fatigue](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

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Folder: Safety Follow Up Diary (1)

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[Muscle aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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[Body aches](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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[Headache](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:32:44

[New loss of taste](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[New loss of smell](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Sore throat](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Congestion](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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Generated On: 09 Jun 2021 17:32:44

[Runny nose](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

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[Nausea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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[Vomiting](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Diarrhea](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Please 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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[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)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
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Folder: Safety Follow Up Diary (1)

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[Date and time of submission](#)

Audit	User	Time (GMT)
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Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Follow Up Diary (1)

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[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '15 Nov 2020 00:01'	System	04 Aug 2020 20:00:44

US3412125

Folder: Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	24 Apr 2021 03:07:00
DataPoint activated (WR#5335027)	System	01 Apr 2021 17:41:56
Amendment Manager: DataPoint Inactivated.	System	19 Nov 2020 12:44:27
Data entry locked.	System	04 Aug 2020 20:00:44
User entered '19 Nov 2020 23:59'	System	04 Aug 2020 20:00:44

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 110'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 Nov 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

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 12:44:27
Amendment Manager: User entered '23 Nov 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 117'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 Nov 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 Nov 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 124'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Dec 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Dec 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 131'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Dec 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Dec 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 138'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 Dec 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Dec 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 145'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 Dec 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Dec 2020 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 152'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '31 Dec 2020 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Jan 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 159'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Jan 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Jan 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 166'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Jan 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Jan 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 173'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Jan 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Jan 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 180'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Jan 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Feb 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 187'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Feb 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Feb 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 194'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Feb 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Feb 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 201'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Feb 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Feb 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 208'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Feb 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Mar 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 215'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Mar 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Mar 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 222'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Mar 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Mar 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 229'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Mar 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Mar 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 236'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Mar 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Mar 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 243'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Apr 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 Apr 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 250'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Apr 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 Apr 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 257'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Apr 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 Apr 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 264'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Apr 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 Apr 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 271'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Apr 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 May 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 278'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 May 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 May 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 285'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '13 May 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 May 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 292'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '20 May 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 May 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 299'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '27 May 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '31 May 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 306'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Jun 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Jun 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 313'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Jun 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Jun 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 320'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 Jun 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Jun 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 327'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 Jun 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Jun 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 334'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Jul 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 Jul 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 341'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Jul 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 Jul 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 348'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Jul 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 Jul 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 355'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Jul 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 Jul 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 362'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Jul 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '02 Aug 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 369'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 Aug 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '09 Aug 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 376'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 Aug 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '16 Aug 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 383'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 Aug 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '23 Aug 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 390'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 Aug 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 Aug 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 397'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '02 Sep 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 Sep 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 404'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '09 Sep 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '13 Sep 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 411'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '16 Sep 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '20 Sep 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 418'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '23 Sep 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '27 Sep 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 425'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 Sep 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Oct 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 432'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Oct 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Oct 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 439'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Oct 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Oct 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 446'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Oct 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Oct 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 453'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Oct 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Nov 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 460'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Nov 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Nov 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 467'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Nov 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Nov 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 474'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Nov 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Nov 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 481'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Nov 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Nov 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 488'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '02 Dec 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 Dec 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 495'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '09 Dec 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '13 Dec 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 502'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '16 Dec 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '20 Dec 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 509'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '23 Dec 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '27 Dec 2021 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 516'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 Dec 2021 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Jan 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 523'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 Jan 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Jan 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 530'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '13 Jan 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 Jan 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 537'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '20 Jan 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 Jan 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 544'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '27 Jan 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '31 Jan 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 551'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Feb 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Feb 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 558'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Feb 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Feb 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 565'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 Feb 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Feb 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 572'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 Feb 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Feb 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 579'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Mar 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Mar 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 586'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Mar 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Mar 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 593'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '17 Mar 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Mar 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 600'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '24 Mar 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Mar 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 607'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '31 Mar 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Apr 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 614'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Apr 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Apr 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 621'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Apr 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Apr 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 628'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Apr 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Apr 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 635'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Apr 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '02 May 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 642'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 May 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '09 May 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 649'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 May 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '16 May 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 656'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 May 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '23 May 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 663'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 May 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 May 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 670'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '02 Jun 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 Jun 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 677'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '09 Jun 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '13 Jun 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 684'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '16 Jun 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '20 Jun 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 691'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '23 Jun 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '27 Jun 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 698'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '30 Jun 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Jul 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 705'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '07 Jul 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Jul 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 712'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '14 Jul 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Jul 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 719'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '21 Jul 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Jul 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 726'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '28 Jul 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Aug 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 733'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '04 Aug 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Aug 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 740'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '11 Aug 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Aug 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 747'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '18 Aug 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Aug 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 754'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '25 Aug 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Aug 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 761'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '01 Sep 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '05 Sep 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 768'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '08 Sep 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '12 Sep 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 775'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '15 Sep 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '19 Sep 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 782'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '22 Sep 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '26 Sep 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 789'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '29 Sep 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '03 Oct 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

TIMEPOINT

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered 'Day 796'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Open Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '06 Oct 2022 00:01'	System	19 Nov 2020 12:44:27

US3412125

Folder: New Safety Follow Up Diary (1)

Form: Safety Follow Up Diary

Generated On: 09 Jun 2021 17:32:44

[Patient Cloud Close Date & Time](#)

Audit	User	Time (GMT)
Amendment Manager: Data entry locked.	System	19 Nov 2020 12:44:27
Amendment Manager: User entered '10 Oct 2022 23:59'	System	19 Nov 2020 12:44:27

US3412125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 12:34:28
	(b) (4)	

US3412125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:34:28
	(b) (4)	

US3412125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:34:28
	(b) (4)	

US3412125

Folder: Safety Call Day 85 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'Site reached out to subject and left multiple voicemails after receiving a safety follow up alert on 07oct2020. Site did not attempt this call as subject had not responded to any previous attempts.'	Andrea Newlands (b) (4)	29 Mar 2021 12:34:28
	(b) (4)	

US3412125

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 12:34:33
	(b) (4)	

US3412125

Folder: Safety Call Day 85 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 12:34:33

US3412125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 12:35:29
	(b) (4)	

US3412125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:35:29
	(b) (4)	

US3412125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:35:29
	(b) (4)	

US3412125

Folder: Safety Call Day 119 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered 'Site did not attempt contact as subject had been unresponsive since their motor vehicle accident on 08aug2020.'	Andrea Newlands (b) (4)	29 Mar 2021 12:35:29
	(b) (4)	

US3412125

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 12:35:34
	(b) (4)	

US3412125

Folder: Safety Call Day 119 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 12:35:34

US3412125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 12:35:41
	(b) (4)	

US3412125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:35:41
	(b) (4)	

US3412125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:35:41
	(b) (4)	

US3412125

Folder: Safety Call Day 149 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered 'Site did not attempt contact as subject had been unresponsive since their motor vehicle accident on 08aug2020.'	Andrea Newlands (b) (4)	29 Mar 2021 12:35:41
	(b) (4)	

US3412125

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:41:00
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:36:59
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 12:35:46
	(b) (4)	

US3412125

Folder: Safety Call Day 149 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 12:41:00
User entered empty.	System	29 Mar 2021 12:36:59
User entered 'I'	System	29 Mar 2021 12:35:46

US3412125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Was Contact Attempted?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 12:37:07
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 12:37:07
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:37:07
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 12:36:54
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:36:54
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	29 Mar 2021 12:35:59
	(b) (4)	

US3412125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

Date of Contact or Contact Attempt (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:35:59
	(b) (4)	

US3412125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Please select one status for the follow-up contact](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	29 Mar 2021 12:35:59
	(b) (4)	

US3412125

Folder: Safety Call Day 179 (1)

Form: Safety Call

Generated On: 09 Jun 2021 17:32:44

[Comments](#)

If Contact Not Made, please provide Comments

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered 'Site inadvertently did not resume safety calls after she came into site for unblinding on 22jan2021.' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:40:53
	(b) (4)	
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:36:54
	(b) (4)	
User entered 'Site did not attempt contact as subject had been unresponsive since their motor vehicle accident on 08aug2020.'	Andrea Newlands (b) (4)	29 Mar 2021 12:35:59
	(b) (4)	

US3412125

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:41:15
	(b) (4)	
User closed query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 12:37:04
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	29 Mar 2021 12:37:04
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:37:04
	(b) (4)	
User opened query 'Data is required. Please complete.' (Site from System).	System	29 Mar 2021 12:36:47
User entered empty; reason for change Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:36:47
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	29 Mar 2021 12:36:38
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	29 Mar 2021 12:36:07
	(b) (4)	

US3412125

Folder: Safety Call Day 179 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered 'I'	System	29 Mar 2021 12:41:15
User entered empty.	System	29 Mar 2021 12:36:38
User entered 'I'	System	29 Mar 2021 12:36:07

US3412125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	31 Mar 2021 15:08:45
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:45
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:45
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Folder OID](#)

Audit	User	Time (GMT)
User entered 'VISIT4'	System	31 Mar 2021 15:08:45

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Were vital signs assessed?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	31 Mar 2021 15:08:51
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Date of assessment (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:51
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4) (b) (4)	16 Apr 2021 14:22:26
User entered empty.	Steven Anderson (b) (4) (b) (4)	31 Mar 2021 15:08:51

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:08:51

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Temperature (xxx.x)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:51
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Route of measurement](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:51
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[If Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:51
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Pulse \(xxx\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:51
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Pulse units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:08:51

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:51
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Respiratory Rate units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:08:51

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Systolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:51
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Systolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:08:51

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

Diastolic Blood Pressure (xxx)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:51
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Vital Signs

Generated On: 09 Jun 2021 17:32:44

[Diastolic Blood Pressure units](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:08:51

US3412125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:32:44

Was the physical examination performed?

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	31 Mar 2021 15:08:55
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Physical Examination

Generated On: 09 Jun 2021 17:32:44

Date of examination (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:55
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'No (N)'	Steven Anderson (b) (4)	31 Mar 2021 15:08:59
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:59
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

Collection time (00:00-23:59)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered empty.	Steven Anderson (b) (4)	31 Mar 2021 15:08:59
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:08:59

US3412125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Is the participant continuing to the next visit?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:26
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Steven Anderson (b) (4)	31 Mar 2021 15:09:20
	(b) (4)	
User entered 'Yes (Y)'	Steven Anderson (b) (4)	31 Mar 2021 15:09:12
	(b) (4)	

US3412125

Folder: Visit 4 Day 209 (1)

Form: Continuing

Generated On: 09 Jun 2021 17:32:44

[Continuing Flag](#)

Audit	User	Time (GMT)
User entered empty.	System	31 Mar 2021 15:09:20
User entered '1'	System	31 Mar 2021 15:09:12

US3412125

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

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Was this visit performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	12 Feb 2021 13:20:56

US3412125

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

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered '22 Jan 2021'	Andrea Newlands (b) (4)	12 Feb 2021 13:20:56

US3412125

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

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'Clinic (Clinic)'	Andrea Newlands (b) (4)	12 Feb 2021 13:20:56

US3412125

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

Form: Visit Date

Generated On: 09 Jun 2021 17:32:44

[Folder OID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User entered 'UNBLND_DECIDE'	System	12 Feb 2021 13:20:56

US3412125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:44

Date of updated informed consent (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered '13 Jan 2021'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:23

US3412125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:44

[N/A - Subject Unblinded under Amendment 5 and Discontinued from Study](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered '0' WR# 5295537	(b) (4)	10 Mar 2021 16:55:28
Amendment Manager inserted this DataPoint.	System	06 Mar 2021 11:24:42

US3412125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:44

[Was the participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:23

US3412125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:44

[Under what version of the Protocol was the Participant unblinded?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
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 11:24:42

US3412125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:44

Date of unblinding (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered '22 Jan 2021'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:23

US3412125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:44

[Participant randomization assignment](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:23

US3412125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:44

[Actual Dose 1](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:23

US3412125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:44

[Actual Dose 2](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'mRNA-1273 (mRNA-1273)'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:23

US3412125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:44

[Will participant receive mRNA-1273?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'No (N)'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:23

US3412125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:44

[Placebo Only Flag](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User entered empty.	System	12 Feb 2021 13:23:23

US3412125

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

Form: Unblinding

Generated On: 09 Jun 2021 17:32:44

[Continuing with mRNA-1273](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User entered empty.	System	12 Feb 2021 13:23:23

US3412125

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:42

US3412125

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered '22 Jan 2021'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:42

US3412125

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

[Collection time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered '14:00'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:42

US3412125

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

Form: Immunogenicity Assessment

Generated On: 09 Jun 2021 17:32:44

[Collection date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User entered '22 Jan 2021 14:00'	System	12 Feb 2021 13:23:42

US3412125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:32:44

[Was the sample collected?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:58

US3412125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:32:44

Collection date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered '22 Jan 2021'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:58

US3412125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:32:44

Collection time (00:00 - 23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
User entered '14:02'	Andrea Newlands (b) (4)	12 Feb 2021 13:23:58

US3412125

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

Form: Central Laboratory - Nasopharyngeal Swab (Single)

Generated On: 09 Jun 2021 17:32:44

[Collection Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	29 Apr 2021 14:38:23
User entered '22 Jan 2021 14:02'	System	12 Feb 2021 13:23:58

US3412125

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:32:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:31
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).		16 Apr 2021 10:59:44
User closed query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).		16 Apr 2021 10:59:41
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'per subject these are consistent with her baseline so it does not qualify as an AE' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:39:00
Query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' answered with 'per subject these are consistent with her baseline so it does not qualify as an AE' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:38:58
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of MUSCLE ACHES persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM).	(b) (4), (b) (6)	21 Mar 2021 11:50:14

US3412125

Folder: Adverse Events

Form: Adverse Events Summary

Generated On: 09 Jun 2021 17:32:44

[Did the participant experience any adverse events?](#)

Audit	User	Time (GMT)
User opened query 'Per DM CLR: Please note, Per Diary Dose 1 Record, symptom of JOINT ACHES persist beyond Day 7 (start date: Day 3; end date: Day 8). Review if this should be recorded as a Solicited Adverse Reaction per protocol 8.3.4 and update AE eCRF as appropriate. Else, provide clarification.' (Site from DM). User signature succeeded.	(b) (4), (b) (6)	21 Mar 2021 11:50:08
	Richard Powell (b) (4)	15 Mar 2021 15:30:59
User closed query 'Not added as AEs - please update and add to AE since lasted beyond Day 7' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 00:09:32
User closed query 'Subject had hyperglycemia and hyponatremia during hospitalization - please review source and add AEs' (Site from CRA).		10 Nov 2020 00:09:29
Query 'Not added as AEs - please update and add to AE since lasted beyond Day 7' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:30:59
Query 'Subject had hyperglycemia and hyponatremia during hospitalization - please review source and add AEs' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:30:46
User opened query 'Not added as AEs - please update and add to AE since lasted beyond Day 7' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:53:24
User closed query 'Per Dose 1 diary, subject had muscle aches and joint aches Day 3 - Day 8 Please review diary/source and capture as AE since beyond Day 7' (Site from CRA).		22 Oct 2020 18:53:24
User opened query 'Subject had hyperglycemia and hyponatremia during hospitalization - please review source and add AEs' (Site from CRA).		22 Oct 2020 18:52:17
Query 'Per Dose 1 diary, subject had muscle aches and joint aches Day 3 - Day 8 Please review diary/source and capture as AE since beyond Day 7' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 14:44:33
User opened query 'Per Dose 1 diary, subject had muscle aches and joint aches Day 3 - Day 8 Please review diary/source and capture as AE since beyond Day 7' (Site from CRA).	(b) (4), (b) (6)	25 Sep 2020 13:38:24
User entered 'Yes (Y)'		09 Sep 2020 14:05:03

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.		10 Sep 2020 16:58:49
User entered 'USA-US061-2020-mRNA-1273-P301000005'	System	10 Sep 2020 16:58:33
User entered 'New'	(b) (4), (b) (6)	10 Sep 2020 16:58:33

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'PV query: Please clarify the event reported as MVA. Please define MVA. ' (Site from Safety).		22 Sep 2020 13:08:37
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 13:17:43
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	21 Sep 2020 13:17:43
Data point term sent to Coder	System	21 Sep 2020 13:17:02
Query 'PV query: Please clarify the event reported as MVA. Please define MVA. ' answered with 'motor vehicle accident ' (Site from Safety).	Mylene Asmar-Rios (b) (4)	21 Sep 2020 13:16:25
Coding entries removed.	Mylene Asmar-Rios (b) (4)	21 Sep 2020 13:16:08
User entered 'Motor Vehicle Accident' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Sep 2020 13:16:08
User opened query 'PV query: Please clarify the event reported as MVA. Please define MVA. ' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:21:11
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Non-site specific injuries NEC, PT: Road traffic accident, LLT: Motor vehicle accident - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 10:22:34
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	10 Sep 2020 10:22:34
Data point term sent to Coder	System	09 Sep 2020 14:09:11
User entered 'MVA'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Sep 2020 14:16:05
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4), (b) (6)	09 Sep 2020 14:16:05
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	09 Sep 2020 14:09:01
User entered '08 Sep ' (non-conformant).	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:49:12
User entered 'Yes (Y)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'Per DM CLR-RQ: Site's response noted. However, a Motor Vehicle Accident is not expected to have a duration of more than a single date. The injuries from the accident might be ongoing but the event of the motor vehicle accident is just a one time event and not expected to have a duration of more than 1 day. Please review and update as appropriate or provide further clarification.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	23 Nov 2020 04:15:51
User closed query 'As discussed, motor vehicle accident should have a single stop and start date that is a single event. Please have PI review. ' (Site from CRA).		19 Nov 2020 19:46:37
Query 'As discussed, motor vehicle accident should have a single stop and start date that is a single event. Please have PI review. ' answered with 'This date has been changed and agreed upon that even though medical records state a separate start and end date that the action of the vehicle accident should have the same start and end date.' (Site from CRA).	Steven Anderson (b) (4)	18 Nov 2020 21:29:51
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	18 Nov 2020 21:28:55
User opened query 'As discussed, motor vehicle accident should have a single stop and start date that is a single event. Please have PI review. ' (Site from CRA).	(b) (4), (b) (6)	18 Nov 2020 16:37:32
Query 'Please discuss with PI as MVA is a single event and should have same start and stop date' canceled (Site from CRA).		10 Nov 2020 00:10:53
User opened query 'Please discuss with PI as MVA is a single event and should have same start and stop date' (Site from CRA).		10 Nov 2020 00:10:37
User closed query 'Should stop date be 8 Sep 2020 since MVA is a single event?' (Site from CRA).		10 Nov 2020 00:10:37

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Query 'Per DM CLR-RQ: Site's response noted. However, a Motor Vehicle Accident is not expected to have a duration of more than a single date. The injuries from the accident might be ongoing but the event of the motor vehicle accident is just a one time event and not expected to have a duration of more than 1 day. Please review and update as appropriate or provide further clarification.' answered with 'as per hospital records and SUB-I discretion the AE date will not be changed as it is stated on hospital discharge date started on 08 sep 2020 and date resolved 01 oct 2020' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:55:00
User opened query 'Per DM CLR-RQ: Site's response noted. However, a Motor Vehicle Accident is not expected to have a duration of more than a single date. The injuries from the accident might be ongoing but the event of the motor vehicle accident is just a one time event and not expected to have a duration of more than 1 day. Please review and update as appropriate or provide further clarification.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:07:24
Query 'Should stop date be 8 Sep 2020 since MVA is a single event?' answered with 'as per hospital discharge papers date resolved 01 oct 2020' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:14:51
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 18:35:02
DataPoint Verified.		22 Oct 2020 18:33:49
User opened query 'Should stop date be 8 Sep 2020 since MVA is a single event?' (Site from CRA).		22 Oct 2020 18:33:35
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	16 Oct 2020 15:49:12
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	16 Oct 2020 15:49:12
User entered '01 Oct 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:49:12

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User opened query 'Outcome is Recovered/Resolved, System Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System). User entered empty.	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[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)	21 Dec 2020 22:26:02
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).		17 Sep 2020 15:19:50
User entered empty.	System	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1' reason for change: Data Entry Error		09 Sep 2020 14:17:25
User entered '0' reason for change: Data Entry Error		09 Sep 2020 14:16:05
User entered '1'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Requires inpatient or prolongation of existing Hospitalization is checked, however Hospital Admission Date, Hospital Discharge Date, or Admitted to ICU? is missing. Please review and reconcile.' (Site from System).	(b) (4), (b) (6)	10 Sep 2020 08:48:31
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 'Will provide further information when available ' (Site from System).		09 Sep 2020 14:17:14
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	09 Sep 2020 14:09:01
User entered '1'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 17:02:23
User closed query 'MOTOR VEHICLE ACCIDENT PV Query: Please consider updating discharge date of event to 01Oct2021 when the subject was discharged.' (Site from Safety).		20 Apr 2021 14:41:03
Query 'MOTOR VEHICLE ACCIDENT PV Query: Please consider updating discharge date of event to 01Oct2021 when the subject was discharged.' answered with 'this has been updated to 01Oct2020 when subject was discharged from the hospital' (Site from Safety).	Steven Anderson (b) (4)	19 Apr 2021 13:55:44
User entered '01 Oct 2020' reason for change: Data Entry Error	(b) (4)	
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 18:28:17
DataPoint Verified.		16 Apr 2021 18:25:35
User opened query 'MOTOR VEHICLE ACCIDENT PV Query: Please consider updating discharge date of event to 01Oct2021 when the subject was discharged.' (Site from Safety).		16 Apr 2021 14:32:17
DataPoint Un-verified.	Melissa Fuson (b) (4)	17 Dec 2020 17:01:35
User entered '08 Sep 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 17:01:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).		19 Oct 2020 14:04:49
Query 'PV Query: Please provide the hospital discharge date when available.' answered with '01 oct 2020' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:49:25
User entered '01 Oct 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:47:46
User opened query 'PV Query: Please provide the hospital discharge date when available.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:20:48
User entered empty.		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4)	19 Oct 2020 14:03:55
Query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' answered with 'yes ICU' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:49:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:47:46
User closed query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	(b) (4), (b) (6)	21 Sep 2020 06:59:55
User opened query 'PV Query: Please confirm if the subject required admission to the intensive care unit.' (Site from Safety).	(b) (4), (b) (6)	17 Sep 2020 15:20:58
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.' answered with 'Will update when hospital records are available ' (Site from System).	(b) (4), (b) (6)	09 Sep 2020 14:13:41
User opened query 'Admitted to ICU? is Unknown. However, this data must be collected. Please leave this query open until the response can be updated to Yes or No.' (Site from System).	System	09 Sep 2020 14:09:01
User entered 'Unknown (UNK)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

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Folder: Adverse Events

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Admitted to ICU? is Yes, however System Number of Days in ICU is missing. Please review and reconcile.' (Site from System).		16 Oct 2020 15:49:46
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).		16 Oct 2020 15:49:46
User entered '10' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:49:46
User opened query 'Admitted to ICU? is Yes, however Number of Days in ICU is missing. Please review and reconcile.' (Site from System).	System	16 Oct 2020 15:47:46
User entered empty.	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'		09 Sep 2020 14:09:01

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Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Applicable (NOT APPLICABLE)'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:37:50
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).	(b) (4) (b) (4), (b) (6)	19 Oct 2020 14:05:02
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 'tracheostomy, bronchoscopy, endoscopic gastrostomy tube placement, closed right tibia-fibula fracture, con meds updated' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 16:13:52
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios	16 Oct 2020 15:47:46
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) (4), (b) (6)	17 Sep 2020 15:20:38
User entered '1'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:33:56
Query 'Conmeds related to this AE are recorded. Please update as appropriate' canceled (Site from CRA).		18 Nov 2020 16:33:49
User opened query 'Conmeds related to this AE are recorded. Please update as appropriate' (Site from CRA).		18 Nov 2020 16:33:04
DataPoint Un-verified.		18 Nov 2020 16:32:43
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:37:50
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	16 Oct 2020 15:47:46
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	18 Nov 2020 16:33:55
Query 'Concomitant procedures related to this AE are recorded. Please update as appropriate' canceled (Site from CRA).		18 Nov 2020 16:33:50
User opened query 'Concomitant procedures related to this AE are recorded. Please update as appropriate' (Site from CRA).		18 Nov 2020 16:33:17
DataPoint Un-verified.		18 Nov 2020 16:32:44
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:37:50
	(b) (4)	
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	16 Oct 2020 15:47:46
	(b) (4)	
User entered '0'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
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).	(b) (4), (b) (6)	19 Oct 2020 14:05:08
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 'updated' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:50:24
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:47:46
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)	17 Sep 2020 15:20:07
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	09 Sep 2020 14:09:01

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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)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User closed query 'Per CDM re-query: Response indicates 'updated; However all the procedures mentioned in the narrative (SUBTOTAL COLECTOMY WITH ILEORECTAL ANASTOMYSIS AND SUBSEQUENT VENTRAL HERNIA REPAIR WITH PERMANENT MESH) doesn't appear to be reflecting in the MH eCRF. Please review and update all the procedures mentioned in Narrative has been added else add in MH as appropriate else clarify.' (Site from DM). Query 'Per CDM re-query: Response indicates 'updated; However all the procedures mentioned in the narrative (SUBTOTAL COLECTOMY WITH ILEORECTAL ANASTOMYSIS AND SUBSEQUENT VENTRAL HERNIA REPAIR WITH PERMANENT MESH) doesn't appear to be reflecting in the MH eCRF. Please review and update all the procedures mentioned in Narrative has been added else add in MH as appropriate else clarify.' answered with 'These are in the medhx	Andrea Newlands (b) (4)	26 Feb 2021 04:38:46
SUBTOTAL COLECTOMY = RUPTURED DIVERTICULUM REPAIR;		
ILEORECTAL ANASTOMYSIS = ILEOSTOMY and ILEOSTOMY REVERSAL;		
VENTRAL HERNIA REPAIR WITH PERMANENT MESH = ABDOMINAL HERNIA REPAIR' (Site from DM). User closed query 'Per DM CLR: SAE Narrative = THE PATIENT ALSO HAS AN EXTENSIVE ABDOMINAL SURGICAL HISTORY INCLUDING SUBTOTAL COLECTOMY WITH ILEORECTAL ANASTOMYSIS AND SUBSEQUENT VENTRAL HERNIA REPAIR WITH PERMANENT MESH.. However, this is not recorded in the Med History eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 05:43:25
PRODUCTION RELEASE (v12.003 EAB) (1725)		2038 of 4013

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'Per CDM re-query: Response indicates 'updated; However all the procedures mentioned in the narrative (SUBTOTAL COLECTOMY WITH ILEORECTAL ANASTOMOSIS AND SUBSEQUENT VENTRAL HERNIA REPAIR WITH PERMANENT MESH) doesn't appear to be reflecting in the MH eCRF. Please review and update all the procedures mentioned in Narrative has been added else add in MH as appropriate else clarify.' (Site from DM).	(b) (4), (b) (6)	22 Feb 2021 05:43:23
User closed query 'Per DM CLR: SAE Narrative = SUBARACHNOID HEMORRHAGE. 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).		22 Feb 2021 05:37:52
User closed query 'Per DM CLR: SAE Narrative = SEIZURE. 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).		22 Feb 2021 05:37:50
User closed query 'Per DM CLR: Narrative indicates that the subject had ventialtory support and entereal nutrition. However, there are no corresponding Concomitant Procedure record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).		22 Feb 2021 05:33:32
Query 'Per DM CLR: Narrative indicates that the subject had ventialtory support and entereal nutrition. However, there are no corresponding Concomitant Procedure record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	(b) (4) 19 Feb 2021 19:58:02

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = THE PATIENT ALSO HAS AN EXTENSIVE ABDOMINAL SURGICAL HISTORY INCLUDING SUBTOTAL COLECTOMY WITH ILEORECTAL ANASTOMOSIS AND SUBSEQUENT VENTRAL HERNIA REPAIR WITH PERMANENT MESH.. However, this is not recorded in the Med History eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	(b) (4) 19 Feb 2021 19:20:28
Query 'Per DM CLR: SAE Narrative = SEIZURE. 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.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	(b) (4) 19 Feb 2021 19:20:06
Query 'Per DM CLR: SAE Narrative = SUBARACHNOID HEMORRHAGE. 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.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	(b) (4) 19 Feb 2021 19:20:02
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' (Site from Safety).	(b) (4), (b) (6)	(b) (4), (b) (6) 16 Feb 2021 20:08:14
User closed query 'Per DM CLR: SAE Narrative = RIGHT TIBIAL AND FIBULAR FRACTURES. 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)	(b) (4), (b) (6) 15 Feb 2021 10:49:28
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 'sent to email 21Feb2021' (Site from Safety).	Andrea Newlands (b) (4)	(b) (4) 12 Feb 2021 21:27:47

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'Per DM CLR: SAE Narrative = RIGHT TIBIAL AND FIBULAR FRACTURES. 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.' answered with 'this is already recorded as a separate AE in AE log line 11' (Site from DM).	Andrea Newlands (b) (4)	12 Feb 2021 14:13:56
User opened query 'Per DM CLR: SAE Narrative = RIGHT TIBIAL AND FIBULAR FRACTURES. 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)	10 Dec 2020 05:12:56
User opened query 'Per DM CLR: SAE Narrative = SEIZURE. 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).		10 Dec 2020 05:12:49
User opened query 'Per DM CLR: SAE Narrative = SUBARACHNOID HEMORRHAGE. 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).		10 Dec 2020 05:12:14
User opened query 'Per DM CLR: SAE Narrative = THE PATIENT ALSO HAS AN EXTENSIVE ABDOMINAL SURGICAL HISTORY INCLUDING SUBTOTAL COLECTOMY WITH ILEORECTAL ANASTOMOSIS AND SUBSEQUENT VENTRAL HERNIA REPAIR WITH PERMANENT MESH.. However, this is not recorded in the Med History eCRF. Please review and ensure that this is captured in the appropriate eCRF. ' (Site from DM).		10 Dec 2020 05:11:58
User opened query 'Per DM CLR: Narrative indicates that the subject had ventialtory support and entereal nutrition. However, there are no corresponding Concomitant Procedure record that match the information. Please update to record the corresponding procedures as appropriate. Otherwise, clarify.' (Site from DM).		28 Nov 2020 17:44:42

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Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
User entered '71 YOF HISTORY OF OPEN SUBTOTAL COLECTOMY WITH END ILEOSTOMY S/P REVERSAL WITH LOWER MIDLINE INCISIONAL HERNIA S/P LAPAROSCOPIC REPAIR WITH MESH WHO PRESENTS S/P MVC ON SEP 8,2020 WITH MULTIPLE INJURIES INCLUDING SUBARACHNOID HEMORRHAGE, BLUNT CEREBROVASCULAR INJURY WITH SUBSEQUENT STROKE AND SEIZURE, GRADE IV LIVER LACERATION, AND RIGHT TIBIAL AND FIBULAR FRACTURES. GIVEN HER ANTICIPATED PROLONGED NEED FOR VENTILATORY SUPPORT AND ENTERAL NUTRITION A TRACHEOSTOMY AND PEG WERE PERFORMED. OF NOTE, THE PATIENT ALSO HAS AN EXTENSIVE ABDOMINAL SURGICAL HISTORY INCLUDING SUBTOTAL COLECTOMY WITH ILEORECTAL ANASTOMOSIS AND SUBSEQUENT VENTRAL HERNIA REPAIR WITH PERMANENT MESH.'	Steven Anderson (b) (4)	24 Nov 2020 19:45:59
reason for change: Data Entry Error		
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)	19 Nov 2020 21:37:29
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).		11 Nov 2020 18:43:38
User closed query 'please update narrative' (Site from CRA).		10 Nov 2020 21:55:46

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so.' answered with 'these records will be sent tomorrow. per monitor all queries must be closed.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 20:56:50
Query 'please update narrative' answered with 'narrative has been updated' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 20:56:10
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 20:55:43
User entered '71 yoF history of open subtotal colectomy with end ileostomy s/p reversal with lower midline incisional hernia s/p laparoscopic repair with mesh who presents s/p MVC on sep 8,2020 with multiple injuries including subarachnoid hemorrhage, blunt cerebrovascular injury with subsequent stroke and seizure, grade v liver laceration, and right tibial and fibular fractures. Given her anticipated prolonged need for ventilatory support and enteral nutrition a tracheostomy and PEG were performed. Of note, the patient also has an extensive abdominal surgical history including subtotal colectomy with ileorectal anastomosis and subsequent ventral hernia repair with permanent mesh.' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 20:55:43
User opened query 'please update narrative' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:14:48
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).		30 Oct 2020 16:30:37
DataPoint Verified.		22 Oct 2020 18:33:49
User closed query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' (Site from Safety).		21 Oct 2020 13:54:17

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Folder: Adverse Events

Form: Adverse Events (1)

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please provide any relevant laboratory and diagnostic test results. Please include units and reference ranges if applicable.' answered with 'The hospital discharge paperwork did not include any laboratory results' (Site from Safety).	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:37:16
User closed query 'PV Query: It was reported the subject was in grave condition. Please consider reporting the subject's injuries as additional SAEs. It is the subject's injuries that led to life-threatening, grave condition, not MVA.' (Site from Safety).	(b) (4), (b) (6)	19 Oct 2020 14:05:24
User closed query 'PV Query: Please clarify if subject was driver for motor vehicle accident. If so, did a medical condition precipitate a driver error?' (Site from Safety).		19 Oct 2020 14:04:57
Query 'PV Query: It was reported the subject was in grave condition. Please consider reporting the subject's injuries as additional SAEs. It is the subject's injuries that led to life-threatening, grave condition, not MVA.' answered with 'updated' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 16:14:30
Query 'PV Query: Please clarify if subject was driver for motor vehicle accident. If so, did a medical condition precipitate a driver error?' answered with 'subject did not have a medical that caused this motor vehicle accident' (Site from Safety).	Mylene Asmar-Rios (b) (4)	16 Oct 2020 15:56:26
User opened query 'PV Query: It was reported the subject was in grave condition. Please consider reporting the subject's injuries as additional SAEs. It is the subject's injuries that led to life-threatening, grave condition, not MVA.' (Site from Safety).	(b) (4), (b) (6)	01 Oct 2020 17:07:42
User opened query 'PV Query: Please clarify if subject was driver for motor vehicle accident. If so, did a medical condition precipitate a driver error?' (Site from Safety).		17 Sep 2020 15:21:34
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).		17 Sep 2020 15:20:25
User entered 'Subjects spouse called stating that subject was in a MVA on 08sep2020 and in grave condition. Will request medical records.'		09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (1)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	16 Oct 2020 15:47:46
User entered '0'	System	09 Sep 2020 14:09:01

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.		20 Oct 2020 12:35:11
User entered 'USA-US061-2020-mRNA-1273-P301000005'		20 Oct 2020 12:35:06

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Injuries NEC, HLT: Cerebral injuries NEC, PT: Craniocerebral injury, LLT: Traumatic brain injury - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:41:31
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 20:41:31
Data point term sent to Coder	System	19 Oct 2020 20:40:29
User entered 'Traumatic brain injury'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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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)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '23 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	19 Oct 2020 20:40:31
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	19 Oct 2020 20:40:31
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	19 Oct 2020 20:39:38
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:39:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Oct 2020 20:40:31
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Oct 2020 20:39:38
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		19 Oct 2020 20:40:31
Query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		19 Oct 2020 20:40:31
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:40:31
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	19 Oct 2020 20:39:38
User entered '0'	Mylene Asmar-Rios	19 Oct 2020 20:39:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	19 Oct 2020 20:40:31
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	19 Oct 2020 20:40:31
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	19 Oct 2020 20:39:38
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

US3412125

Folder: Adverse Events

Form: Adverse Events (2)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	05 Nov 2020 15:15:35
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:24:20
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:24:20
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:39:38
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 12:08:47
	(b) (4), (b) (6)	11 Nov 2020 04:53:04
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'this has been updated to indicate con meds were taken for it' (Site from DM). User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 21:24:02
	(b) (4)	
DataPoint Un-verified.	(b) (4)	10 Nov 2020 21:19:47
	(b) (4), (b) (6)	05 Nov 2020 15:17:21
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.		28 Oct 2020 15:13:27
		22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:56:50
User closed query 'per source amantadine HCL given for traumatic brain injury - please confirm and update action taken on thsi CRF' (Site from CRA).	(b) (4), (b) (6)	10 Nov 2020 21:56:47
Query 'per source amantadine HCL given for traumatic brain injury - please confirm and update action taken on thsi CRF' answered with 'this has been updated to indicate con meds were taken for it' (Site from CRA).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 21:24:06
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 21:19:47
DataPoint Un-verified.	(b) (4) (b) (4), (b) (6)	05 Nov 2020 15:17:23
User opened query 'per source amantadine HCL given for traumatic brain injury - please confirm and update action taken on thsi CRF' (Site from CRA).	(b) (4), (b) (6)	05 Nov 2020 15:17:19
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:30:40
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:41:40
User entered 'Recovered/Resolved with Sequelae (RECOVERED/RESOLVED WITH SEQUELAE)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:40:31
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

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If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'function of subject confusion, weakness' reason for change: Data Entry Error	Mylene Asmar-Rios	21 Oct 2020 16:30:40
User closed query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	(b) (4)	
User opened query 'Outcome Recovered/Resolved with Sequelae, but specify the sequelae is missing. Please provide.' (Site from System).	System	19 Oct 2020 20:41:40
User entered empty.	System	19 Oct 2020 20:40:31
	Mylene Asmar-Rios	19 Oct 2020 20:39:38
	(b) (4)	

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[Narrative](#)

Audit	User	Time (GMT)
Query 'PV Query: Please confirm date for MRI that showed multiple left hemispheric embolic infarcts and TTE that demonstrated normal LV systolic function. If unknown, please indicate so.' canceled (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 14:07:24
User opened query 'PV Query: Please confirm date for MRI that showed multiple left hemispheric embolic infarcts and TTE that demonstrated normal LV systolic function. If unknown, please indicate so.' (Site from Safety).		23 Feb 2021 14:06:56
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:41:58
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Oct 2020 20:41:40
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Oct 2020 20:41:40
User entered 'Subject was in Moto Vehicle Accident' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:41:40
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Oct 2020 20:39:38
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:39:38

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Folder: Adverse Events

Form: Adverse Events (2)

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[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 20:39:38

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Folder: Adverse Events

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.		20 Oct 2020 12:35:58
User entered 'USA-US061-2020-mRNA-1273-P301000005'		20 Oct 2020 12:35:53

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Folder: Adverse Events

Form: Adverse Events (3)

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Embolic stroke, LLT: Embolic stroke - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 23:28:25
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 23:28:25
Data point term sent to Coder	System	19 Oct 2020 20:44:33
User entered 'Multiple left hemisphere Embolic Infarct'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:43:49
	(b) (4)	

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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	19 Oct 2020 20:43:49

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:26:29
User closed 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. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:45:40
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. Please do not reply to this query until the information is obtained.' answered with 'Site is closing all queries like this. This reflects back on us stating we have open queries and we get told to do them consistently. site will update information if these SAE's close' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:26:01
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. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:13:45
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:43:49
	(b) (4)	

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Folder: Adverse Events

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[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. Please do not reply to this query until the information is obtained. ' canceled (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:26:24
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. Please do not reply to this query until the information is obtained. ' (Site from Safety).		19 Nov 2020 21:33:10
User entered empty.	System	19 Oct 2020 20:43:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'I'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
User closed query 'PV query: Please confirm admission date as MULTIPLE LEFT HEMISPHERE EMBOLIC INFARCT has an admission of 03 Sep 2020.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 18:45:49
		11 Nov 2020 04:53:31
User closed query 'hospital admission on 8 Sep 2020 per source - please confirm and correct' (Site from CRA).		11 Nov 2020 04:53:29
Query 'hospital admission on 8 Sep 2020 per source - please confirm and correct' answered with 'date has been updated. all admission date for all SAE's should be 08-sep-2020' (Site from CRA).	Steven Anderson (b) (4)	10 Nov 2020 21:27:41
Query 'PV query: Please confirm admission date as MULTIPLE LEFT HEMISPHERE EMBOLIC INFARCT has an admission of 03 Sep 2020.' answered with 'date has been updated. all admission date for all SAE's should be 08-sep-2020' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:27:38
User entered '08 Sep 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 21:27:18
User opened query 'hospital admission on 8 Sep 2020 per source - please confirm and correct' (Site from CRA). DataPoint Un-verified.	(b) (4), (b) (6)	05 Nov 2020 15:54:06
		05 Nov 2020 15:19:05
User opened query 'PV query: Please confirm admission date as MULTIPLE LEFT HEMISPHERE EMBOLIC INFARCT has an admission of 03 Sep 2020.' (Site from Safety). DataPoint Verified.		23 Oct 2020 12:14:37
		22 Oct 2020 18:33:49
User entered '03 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	13 Feb 2021 16:31:09
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:25:10
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:25:10
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:43:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 12:10:27
DataPoint Verified.		11 Nov 2020 04:53:46
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 22:07:01
User entered '0' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	10 Nov 2020 22:07:01
	(b) (4)	
Query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' answered with 'Per medical records no treatments or procedures were specifically given for this SAE. Subject had multiple conditions that could have resulted in this/ had similar treatments.' (Site from DM).	Steven Anderson (b) (4)	10 Nov 2020 21:36:19
	(b) (4)	
User opened query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:14:28
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	15 Feb 2021 10:47:51
Query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' answered with 'heparin in conmeds' (Site from DM).	Andrea Newlands (b) (4)	12 Feb 2021 14:35:28
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, there is no recorded ConMed that match this AE during this time frame. Please update to record the ConMed treatment for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4)	
Query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed that is indicated for this AE was given after the End date of this AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' canceled (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 17:51:57
User opened query 'Per DM CLR: Other Action Taken = ConMed. However, the corresponding ConMed that is indicated for this AE was given after the End date of this AE. Please reconcile and update applicable details as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Nov 2020 17:51:48
DataPoint Verified.	(b) (4), (b) (6)	28 Nov 2020 17:46:07
DataPoint Un-verified.	(b) (4), (b) (6)	11 Nov 2020 04:53:52
User entered '1' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 22:07:01
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 22:07:01
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 18:33:49
	(b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

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[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
DataPoint Un-verified.	Steven Anderson (b) (4)	09 Apr 2021 14:12:20
User entered 'Not Recovered/Not Resolved (NOT RECOVERED/NOT RESOLVED)' reason for change: Data Entry Error	(b) (4)	
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. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	Steven Anderson (b) (4)	09 Apr 2021 14:12:20
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. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:33:25
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. Please do not reply to this query until the event information has been obtained.' answered with 'Site will not leave this query open. site is being pointed out for leaving these open and being told to address by monitors. site will address once more information has been updated.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:45:58
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. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:37:09
DataPoint Verified.	(b) (4)	
User entered 'Unknown (UNKNOWN)'	(b) (4), (b) (6)	23 Oct 2020 12:14:04
	(b) (4), (b) (6)	22 Oct 2020 18:33:49
	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

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Folder: Adverse Events

Form: Adverse Events (3)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:43:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm date for MRI that showed multiple left hemispheric embolic infarcts and TTE that demonstrated normal LV systolic function. If unknown, please indicate so.' (Site from Safety).	(b) (4), (b) (6)	07 Apr 2021 14:23:22
Query 'PV Query: Please confirm date for MRI that showed multiple left hemispheric embolic infarcts and TTE that demonstrated normal LV systolic function. If unknown, please indicate so.' answered with 'they were in september 2020, exact date is unknown' (Site from Safety).	Andrea Newlands (b) (4)	06 Apr 2021 20:25:28
User opened query 'PV Query: Please confirm date for MRI that showed multiple left hemispheric embolic infarcts and TTE that demonstrated normal LV systolic function. If unknown, please indicate so.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 14:07:46
User closed query 'PV Query: Please send a hospital discharge summary with patient identifiers redacted and subject ID added to Safety_Moderna@iqvia.com or fax to 866.599.1342. Please leave query unanswered until records sent or, if unable to obtain, please state so. ' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 15:32:30
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 12feb2021' (Site from Safety).	Andrea Newlands (b) (4)	19 Feb 2021 20:00:25
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. Please do not reply to this query until the information is obtained. (for events: acute post hemorrhagic anemia, cervical 7 fracture, multiple left hemisphere embolic infarct, left intercarotid artery, and grade IV liver laceration) ' canceled (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:26:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
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. Please do not reply to this query until the event information has been obtained. (for events: acute post hemorrhagic anemia, cervical 7 fracture, multiple left hemisphere embolic infarct, left intercarotid artery, and grade IV liver laceration) ' canceled (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:26:47
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).		02 Dec 2020 18:01:12
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. Please do not reply to this query until the information is obtained. (for events: acute post hemorrhagic anemia, cervical 7 fracture, multiple left hemisphere embolic infarct, left intercarotid artery, and grade IV liver laceration) ' (Site from Safety).		02 Dec 2020 18:00:39
User opened query 'PV query: Please provide the final event outcome, when available. If not expected to resolve, please confirm in your response. If resolution is expected, please keep query open until achieved. Please do not reply to this query until the event information has been obtained. (for events: acute post hemorrhagic anemia, cervical 7 fracture, multiple left hemisphere embolic infarct, left intercarotid artery, and grade IV liver laceration) ' (Site from Safety).		02 Dec 2020 18:00:28
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Subject was in Motor Vehicle Accident'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (3)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 20:43:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.		20 Oct 2020 12:37:03
User entered 'USA-US061-2020-mRNA-1273-P301000005'		20 Oct 2020 12:36:59

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Carotid artery thrombosis, LLT: Carotid artery thrombosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 15:10:02
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Apr 2021 15:10:02
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Coronary artery disorders NEC, PT: Coronary artery thrombosis, LLT: Intraluminal coronary thrombosis - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:10:52
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	17 Nov 2020 04:10:52
User closed query 'PV Query: The current event contains two event terms. Please separate the verbatim term into two SAEs to represent the two events of 'Carotid artery dissection' and 'Carotid artery thrombus'. ' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 18:46:51
Query 'PV Query: The current event contains two event terms. Please separate the verbatim term into two SAEs to represent the two events of 'Carotid artery dissection' and 'Carotid artery thrombus'. ' answered with 'Per medical records this was one diagnosis. Medication was also given to treat both. site will not update to two separate SAE's' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 21:50:34
User opened query 'PV Query: The current event contains two event terms. Please separate the verbatim term into two SAEs to represent the two events of 'Carotid artery dissection' and 'Carotid artery thrombus'. ' (Site from Safety).	(b) (4), (b) (6)	05 Nov 2020 15:24:01
DataPoint Verified.		22 Oct 2020 18:33:49
Data point term sent to Coder	System	21 Oct 2020 15:15:19
User closed query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of LEFT INTERCAROTID ARTERY DISSECTION and one of INTRALUMINAL CORONARY THROMBUS' (Site from System).	System	21 Oct 2020 15:15:10

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
Query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of LEFT INTERCAROTID ARTERY DISSECTION and one of INTRALUMINAL CORONARY THROMBUS' answered with 'its one diagnosis no further breakup needed' (Site from System).	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:15:10
User opened query 'Per CDM Coding: Multiple medical concepts are reported. Please split into separate records, e.g. one of LEFT INTERCAROTID ARTERY DISSECTION and one of INTRALUMINAL CORONARY THROMBUS' (Site from System).	Coder Import (b) (4) (b) (4)	21 Oct 2020 14:37:29
Data point term sent to Coder	System	20 Oct 2020 14:44:43
User closed query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' (Site from System).	System	20 Oct 2020 14:44:21
Query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' answered with 'updated. ' (Site from System).	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 14:44:21
User entered 'LEFT INTERCAROTID ARTERY dissection with intraluminal thrombus' reason for change: Data Entry Error	Jacob sekinger (b) (4) (b) (4)	20 Oct 2020 14:44:10
User opened query 'DM-Coding: The verbatim term appears to be incomplete. Please update the condition/event being reported, alternatively provide more information. ' (Site from System).	Coder Import (b) (4) (b) (4)	20 Oct 2020 08:59:27
Data point term sent to Coder	System	19 Oct 2020 20:50:42
User entered 'Left intercarotid artery'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:49:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:27:17
User closed 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. Please do not reply to this query until the information is obtained. ' (Site from Safety).		11 Nov 2020 18:47:04
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. Please do not reply to this query until the information is obtained. ' answered with 'Site will nto leave this open due to monitors requesting all queries be closed. Site will address once SAE closes' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:44:11
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. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:15:21
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:49:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[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. Please do not reply to this query until the information is obtained. ' canceled (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:27:12
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. Please do not reply to this query until the information is obtained. ' (Site from Safety).		19 Nov 2020 21:34:40
User entered empty.	System	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Oct 2020 20:50:09
User opened query 'Is the adverse event serious is Yes, but seriousness criteria is missing. Please check at least one criteria from the options below.' (Site from System).	System	19 Oct 2020 20:49:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Requires inpatient or prolongation System 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).		19 Oct 2020 20:51:00
Query 'Requires inpatient or prolongation of existing System 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).		19 Oct 2020 20:51:00
User closed query 'Requires inpatient or prolongation System of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).		19 Oct 2020 20:50:09
Query 'Requires inpatient or prolongation of existing System Hospitalization is not checked, but hospitalization data has been provided. Please correct.' answered by data change (Site from System).		19 Oct 2020 20:50:09
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	19 Oct 2020 20:50:09
User entered '1' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:50:09
User opened query 'Requires inpatient or prolongation of existing Hospitalization is not checked, but hospitalization data has been provided. Please correct.' (Site from System).	(b) (4)	19 Oct 2020 20:49:49
User entered '0'	Mylene Asmar-Rios	19 Oct 2020 20:49:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020' reason for change: Data Entry Error	Mylene Asmar-Rios	19 Oct 2020 20:51:00
User entered empty.	(b) (4)	
	Mylene Asmar-Rios	19 Oct 2020 20:49:49
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	19 Oct 2020 20:50:09
Query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' answered by data change (Site from System).	System	19 Oct 2020 20:50:09
User opened query 'Participant was not hospitalized or Admitted to ICU? is No however Number of Days in ICU has been provided. Please review and reconcile.' (Site from System).	System	19 Oct 2020 20:49:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:54:19
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:25:58
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:25:58
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:49:49
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 11:59:19
		11 Nov 2020 04:54:29
Query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' answered with 'this has been updated due to con med being used for this SAE' (Site from DM). DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 21:44:54
	(b) (4)	
	Steven Anderson (b) (4)	10 Nov 2020 21:44:30
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 21:44:30
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = None. However, there is a recorded ConMed that match this AE. Please review and update Other Action Taken as appropriate. Otherwise, clarify.' (Site from DM). Query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' canceled (Site from DM). User opened query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:12:39
		28 Oct 2020 15:11:42
		28 Oct 2020 15:10:45
		22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:54:31
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 21:44:30
User entered '1' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 21:44:30
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
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. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:34:54
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. Please do not reply to this query until the event information has been obtained.' (Site from Safety).		11 Nov 2020 18:47:11
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. Please do not reply to this query until the event information has been obtained.' answered with 'Site will not leave query open. these events may not resolve by end of trial and monitors are requesting all queries closed for SAE. please advise this with internal team before putting another query.' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 21:46:07
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. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:15:37
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
User closed query 'IQVIA Medical query: Please consider whether LEFT INTERCAROTID ARTERY DISSECTION WITH INTRALUMINAL THROMBUS is a single event or multiple events, and update report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	20 Apr 2021 14:42:55
Query 'IQVIA Medical query: Please consider whether LEFT INTERCAROTID ARTERY DISSECTION WITH INTRALUMINAL THROMBUS is a single event or multiple events, and update report if appropriate.' (Site from Safety).	Steven Anderson (b) (4)	19 Apr 2021 14:02:54
Query 'IQVIA Medical query: Please consider whether LEFT INTERCAROTID ARTERY DISSECTION WITH INTRALUMINAL THROMBUS is a single event or multiple events, and update report if appropriate.' answered with 'the PI deemed this as a single event when writing up the SAE' (Site from Safety).	(b) (4)	
User opened query 'IQVIA Medical query: Please consider whether LEFT INTERCAROTID ARTERY DISSECTION WITH INTRALUMINAL THROMBUS is a single event or multiple events, and update report if appropriate.' (Site from Safety).	(b) (4), (b) (6)	16 Apr 2021 14:34:17
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (4)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 20:49:49

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.		20 Oct 2020 12:37:51
User entered 'USA-US061-2020-mRNA-1273-P301000005'		20 Oct 2020 12:37:46

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Spinal fractures and dislocations, PT: Cervical vertebral fracture, LLT: Cervical vertebral fracture C7 - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:51:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:51:31
Data point term sent to Coder	System	19 Oct 2020 20:53:44
User entered 'CERVICAL 7 FRACTURE'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 20:53:01
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Oct 2020 20:53:01
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:53:01
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Oct 2020 20:52:51
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:26:51
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Apr 2021 20:26:51
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User closed 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. Please do not reply to this query until the information is obtained. ' (Site from Safety).		07 Apr 2021 14:24:42
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Apr 2021 20:27:13
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	06 Apr 2021 20:27:13
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. Please do not reply to this query until the information is obtained. ' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	06 Apr 2021 20:26:57
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	06 Apr 2021 20:26:51
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:26:51
User entered '09 Dec 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:26:51
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. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:27:38
User closed 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. Please do not reply to this query until the information is obtained.' (Site from Safety).		11 Nov 2020 18:47:37

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

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. Please do not reply to this query until the information is obtained.' answered with 'Site will not leave query open. these events may not resolve by end of trial and monitors are requesting all queries closed for SAE. please advise this with internal team before putting another query.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:51:05
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. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:12:10
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:52:51
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[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. Please do not reply to this query until the information is obtained. ' canceled (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:27:39
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. Please do not reply to this query until the information is obtained. ' (Site from Safety).		19 Nov 2020 21:31:48
User entered empty.	System	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'I'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

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Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:54:49
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:26:47
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:26:47
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:52:51
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:54:56
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 22:08:44
User entered '1' reason for change: Data Entry Error	(b) (4)	10 Nov 2020 22:08:44
DataPoint Verified.	Steven Anderson (b) (4)	10 Nov 2020 22:08:44
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios	19 Oct 2020 20:52:51
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Take = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 11:59:47
		11 Nov 2020 04:54:55
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'this has been updated due to no con procedure being performed. there was no noted procedures or anything in medical records.' (Site from DM). DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 22:08:50
	(b) (4)	
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 22:08:44
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:08:32
		22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
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. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).		07 Apr 2021 14:25:18
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:27:13
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:27:13
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. Please do not reply to this query until the event information has been obtained. ' answered with 'updated' (Site from Safety).	(b) (4)	
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. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).	Andrea Newlands (b) (4)	06 Apr 2021 20:27:02
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. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:31:17
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. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).		11 Nov 2020 18:47:52

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
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. Please do not reply to this query until the event information has been obtained' answered with 'Site will not leave query open. these events may not resolve by end of trial and monitors are requesting all queries closed for SAE. please advise this with internal team before putting another query.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 21:51:15
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. Please do not reply to this query until the event information has been obtained' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:12:27
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

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[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:52:51
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (5)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 20:52:51

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		16 Apr 2021 18:25:35
Reviewed for Safety.		07 Apr 2021 16:13:11
Un-reviewed for Safety.		07 Apr 2021 16:12:26
DataPoint Un-verified.		07 Apr 2021 16:12:26
User entered empty; reason for change Obvious Correction		07 Apr 2021 16:12:26
DataPoint Verified.		22 Oct 2020 18:33:49
Reviewed for Safety.		20 Oct 2020 12:38:51
User entered 'USA-US061-2020-mRNA-1273-P301000005'		20 Oct 2020 12:38:43

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Thoracic cage fractures and dislocations, PT: Rib fracture, LLT: Rib fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:11:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	20 Oct 2020 05:11:33
Data point term sent to Coder	System	19 Oct 2020 20:56:51
User entered 'NONDISPLACED RIB FRACTURES RIGHT 1-2'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
User entered empty.	System	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.	(b) (4)	16 Apr 2021 18:25:35
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:28:00
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Apr 2021 20:28:00
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		16 Apr 2021 18:25:35
User closed query 'Outcome is not Recovered/Resolved, Recovered/Resolved with sequelae or Fatal, but End Date is provided. Please correct.' (Site from System).	System	06 Apr 2021 20:28:06
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	06 Apr 2021 20:28:06
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	06 Apr 2021 20:28:00
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:28:00
User entered '19 Dec 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:28:00
User closed 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. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:02:02
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. Please do not reply to this query until the information is obtained.' answered with 'Site will not leave these open anymore due to site being told to close all queries. if these are to be left open there has to be an internal communication between you and monitors.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:09:55
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. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:13:21

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 20:56:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
User entered empty.	System	19 Oct 2020 20:56:28

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		10 Nov 2020 00:12:16
User closed query 'grade 2 per source? Please review and update as appropriate' (Site from CRA).		10 Nov 2020 00:12:14
Query 'grade 2 per source? Please review and update as appropriate' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:16:32
User entered 'Grade 2/Moderate (Grade 2/Moderate)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:16:24
DataPoint Un-verified.	(b) (4), (b) (6)	22 Oct 2020 18:43:04
User opened query 'grade 2 per source? Please review and update as appropriate' (Site from CRA).		22 Oct 2020 18:42:55
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).		27 Oct 2020 12:14:43
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Is the adverse event serious is No, System but seriousness criteria is provided. Please correct.' (Site from System).		21 Oct 2020 15:14:06
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered with 'no SAE' (Site from System).	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:13:48
User opened query 'AE severity is Grade 4, but is the System adverse event serious is No. Please confirm or correct.' (Site from System).		21 Oct 2020 15:07:41
User opened query 'Is the adverse event serious is No, but seriousness criteria is provided. Please correct.' (Site from System).	System	21 Oct 2020 15:07:41
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User closed query 'Requires inpatient or prolongation System 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).		21 Oct 2020 15:14:06
Query 'Requires inpatient or prolongation of existing System 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).		21 Oct 2020 15:14:06
User entered '0' reason for change: Data Entry Error	Mylene Asmar-Rios	21 Oct 2020 15:14:06
	(b) (4)	
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	21 Oct 2020 15:07:41
User entered '1'	Mylene Asmar-Rios	19 Oct 2020 20:56:28
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		29 Dec 2020 20:26:06
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:27:27
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mylene Asmar-Rios	22 Oct 2020 21:27:27
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:56:28
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.	(b) (4)	11 Nov 2020 04:55:25
DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 22:15:08
User entered '1' reason for change: Data Entry Error	(b) (4)	
	Steven Anderson (b) (4)	10 Nov 2020 22:15:08
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios	19 Oct 2020 20:56:28
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
User closed query 'Per DM CLR: Other Action Take = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4)	11 Nov 2020 11:58:22
	(b) (4)	11 Nov 2020 04:55:27
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'site is not noting any procedures performed for this ae. sit ehas changed data' (Site from DM). DataPoint Un-verified.	Steven Anderson (b) (4)	10 Nov 2020 22:15:56
	(b) (4)	
	Steven Anderson (b) (4)	10 Nov 2020 22:15:08
User entered '0' reason for change: Data Entry Error	Steven Anderson (b) (4)	10 Nov 2020 22:15:08
	(b) (4)	
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	28 Oct 2020 15:15:07
	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:28:06
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Andrea Newlands (b) (4)	06 Apr 2021 20:28:06
Data Entry Error	(b) (4)	
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. Please do not reply to this query until the event information has been obtained' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:02:06
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. Please do not reply to this query until the event information has been obtained' answered with 'Site will not leave these open anymore due to site being told to close all queries. if these are to be left open there has to be an internal communication between you and monitors.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:10:03
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. Please do not reply to this query until the event information has been obtained' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:13:06
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

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 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty; reason for change Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:07:41
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
User entered '0'	System	21 Oct 2020 15:07:41
User entered '1'	System	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
User entered '1'	System	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (6)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:01
User entered '1'	System	19 Oct 2020 20:56:28

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.		20 Oct 2020 12:40:03
User entered 'USA-US061-2020-mRNA-1273-P301000005'		20 Oct 2020 12:39:56

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Infections and infestations, HLGT: Bacterial infectious disorders, HLT: Staphylococcal infections, PT: Pneumonia staphylococcal, LLT: Pneumonia MRSA - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:39:29
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 22:39:29
Data point term sent to Coder	System	19 Oct 2020 20:58:54
User entered 'MRSA PNEUMONIA'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '29 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'I'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:55:40
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:28:12
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:28:12
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 20:58:10
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (7)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 20:58:10

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please update the event term to the final diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 15:34:43
Query 'PV Query: Please update the event term to the final diagnosis, when available.' answered with 'updated' (Site from Safety).	(b) (4)	19 Feb 2021 19:10:02
User opened query 'PV Query: Please update the event term to the final diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:38:34
DataPoint Verified.		22 Oct 2020 18:33:49
Reviewed for Safety.		20 Oct 2020 12:40:41
User entered 'USA-US061-2020-mRNA-1273-P301000005'		20 Oct 2020 12:40:37

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User closed query 'PV Query: Please update the even term to the final diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	09 Mar 2021 19:06:01
User closed query 'For coding purposes, this entry references two events that while related, must be reported separately as the combined events are not referenced together in the standard dictionary, please provide a single diagnosis or split and report separately to capture coding for all the term' (Site from Coder).		08 Mar 2021 16:07:41
Query 'PV Query: Please update the event term to the final diagnosis, when available.' answered with 'term was updated from nonstemi vs cardiac contusion to nonstemi - please clarify if further action is needed' (Site from Safety).		08 Mar 2021 15:30:20
User opened query 'PV Query: Please update the event term to the final diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	23 Feb 2021 14:20:42
User closed query 'PV Query: Please update the event term to the final diagnosis, when available.' (Site from Safety).	(b) (4), (b) (6)	22 Feb 2021 15:34:52
User coded data point as SOC: Cardiac disorders, HLT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non STEMI - version MedDRA\23.0.		19 Feb 2021 19:10:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4)	19 Feb 2021 19:10:55
Query 'PV Query: Please update the event term to the final diagnosis, when available.' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	19 Feb 2021 19:10:18
Query 'For coding purposes, this entry references two events that while related, must be reported separately as the combined events are not referenced together in the standard dictionary, please provide a single diagnosis or split and report separately to capture coding for all the term' answered with 'updated' (Site from Coder).	Andrea Newlands (b) (4)	19 Feb 2021 19:10:14
Data point term sent to Coder	System	19 Feb 2021 19:10:14

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Un-verified.	Andrea Newlands (b) (4)	19 Feb 2021 19:09:48
Coding entries removed.	Andrea Newlands (b) (4)	19 Feb 2021 19:09:48
User entered 'NON STEMI' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:09:48
User opened query 'PV Query: Please update the event term to the final diagnosis, when available. ' (Site from Safety).	(b) (4), (b) (6)	02 Dec 2020 18:02:02
User opened query 'For coding purposes, this entry references two events that while related, must be reported separately as the combined events are not referenced together in the standard dictionary, please provide a single diagnosis or split and report separately to capture coding for all the term' (Site from Coder).		30 Nov 2020 19:47:33
User coded data point as SOC: Cardiac disorders, HLGT: Coronary artery disorders, HLT: Ischaemic coronary artery disorders, PT: Acute myocardial infarction, LLT: Non STEMI - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 19:44:01
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	24 Nov 2020 19:44:01
Data point term sent to Coder	System	24 Nov 2020 18:51:12
Query 'For coding purposes, this entry references two events that while related, must be reported separately as the combined events are not referenced together in the standard dictionary, please provide a single diagnosis or split and report separately to capture coding for all the terms.' canceled (Site from System).	Coder Import (b) (4)	24 Nov 2020 18:51:01
User opened query 'For coding purposes, this entry references two events that while related, must be reported separately as the combined events are not referenced together in the standard dictionary, please provide a single diagnosis or split and report separately to capture coding for all the terms.' (Site from System).	Coder Import (b) (4)	23 Nov 2020 14:51:51
User closed query 'PV query: Please update the term "NSTEMI vs cardiac contusion ". Did the subject experience NSTEMI or cardiac contusion or both? If so, please report as applicable.' (Site from Safety).	(b) (4), (b) (6)	11 Nov 2020 19:05:25

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412125

Folder: Adverse Events

Form: Adverse Events (8)

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[Adverse event](#)

Audit	User	Time (GMT)
Query 'PV query: Please update the term "NSTEMI vs cardiac contusion ". Did the subject experience NSTEMI or cardiac contusion or both? If so, please report as applicable.' answered with 'unable to decipher due to medical records.' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:34:05
User opened query 'PV query: Please update the term "NSTEMI vs cardiac contusion ". Did the subject experience NSTEMI or cardiac contusion or both? If so, please report as applicable.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:07:07
DataPoint Verified.		22 Oct 2020 18:33:49
Data point term sent to Coder	System	22 Oct 2020 14:12:58
User closed query 'DM-Coding: Please provide a single confirmed diagnosis (please update to Non STEMI if it was) or record the suspected diagnoses/symptoms separately. ' (Site from System).	System	22 Oct 2020 14:12:05
Query 'DM-Coding: Please provide a single confirmed diagnosis (please update to Non STEMI if it was) or record the suspected diagnoses/symptoms separately. ' answered with 'AS PER HOSPITAL RECORDS NON STEMI VS CARDIAC CONTUSION WAS THE DIAGNOSES GIVEN THEREFORE IT CAN NOT BE BROKEN APART' (Site from System).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:12:05
Data point term sent to Coder	System	22 Oct 2020 14:11:56
User entered 'NON STEMI VS CARDIAC CONTUSION' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:11:21
User opened query 'DM-Coding: Please provide a single confirmed diagnosis (please update to Non STEMI if it was) or record the suspected diagnoses/symptoms separately. ' (Site from System).	Coder Import (b) (4)	22 Oct 2020 08:36:24
Data point term sent to Coder	System	21 Oct 2020 15:16:20
User closed query 'DM-Coding: Please provide a single confirmed diagnosis or record the suspected diagnoses/symptoms separately. ' (Site from System).	System	21 Oct 2020 15:16:19
Query 'DM-Coding: Please provide a single confirmed diagnosis or record the suspected diagnoses/symptoms separately. ' answered with 'its one diagnosis ' (Site from System).	Mylene Asmar-Rios (b) (4)	21 Oct 2020 15:16:19
User opened query 'DM-Coding: Please provide a single confirmed diagnosis or record the suspected diagnoses/symptoms separately. ' (Site from System).	Coder Import (b) (4)	20 Oct 2020 09:04:28

PRODUCTION RELEASE (v12.003
EAB) (1725)

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US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
Data point term sent to Coder	System	19 Oct 2020 21:00:58
User entered 'NSTEMI VS CARDIAC CONTUSION'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 21:00:38
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Oct 2020 16:45:11
User entered 'No (N)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:45:11
User opened query 'Ongoing is Yes, but End Date is provided. Please correct.' (Site from System).	System	21 Oct 2020 16:44:52
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	21 Apr 2021 17:50:10
Query 'Please consider updating stop date to 13 Sep 2020. MIs do not typically last more than 24 hrs' canceled (Site from CRA).	(b) (4), (b) (6)	21 Apr 2021 17:50:07
User entered '13 Sep 2020' reason for change: Data Entry Error	Steven Anderson (b) (4)	20 Apr 2021 18:43:15
User opened query 'Please consider updating stop date to 13 Sep 2020. MIs do not typically last more than 24 hrs' (Site from CRA).	(b) (4), (b) (6)	20 Apr 2021 18:09:17
DataPoint Un-verified.	(b) (4), (b) (6)	20 Apr 2021 18:02:35
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User closed query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	21 Oct 2020 16:44:52
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	21 Oct 2020 16:44:52
User entered '01 Oct 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:44:52
User opened query 'Outcome is Recovered/Resolved, Recovered/Resolved with Sequelae or Fatal, but End Date is missing. Please provide.' (Site from System).	System	21 Oct 2020 16:32:52
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 21:00:38
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'I'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:12:55
User closed query 'Admission 8 Sep 2020 per source? Please review and update accordingly' (Site from CRA).	(b) (4)	10 Nov 2020 00:12:52
Query 'Admission 8 Sep 2020 per source? Please review and update accordingly' answered with 'updated' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:19:09
User entered '08 Sep 2020' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:18:41
User opened query 'Admission 8 Sep 2020 per source? Please review and update accordingly' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:45:32
DataPoint Un-verified.	(b) (4)	22 Oct 2020 18:44:28
DataPoint Verified.	(b) (4)	22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:56:00
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:19:52
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:19:52
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 21:00:38
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

None

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	23 Nov 2020 13:17:18
Query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' answered with 'per medical record cardiologist said she is not a candidate for treatment due to multiple serious injuries.' (Site from DM).	Steven Anderson (b) (4)	10 Nov 2020 22:36:48
User opened query 'Per DM CLR: Please verify if there were treatments given for this Serious AE as treatment is expected. If treatments were given, please update to record accordingly. Otherwise, clarify reason why no treatment was needed.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:16:09
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'I'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:32:52
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

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[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered '1'	System	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (8)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 21:00:38

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.		20 Oct 2020 12:41:19
User entered 'USA-US061-2020-mRNA-1273-P301000005'		20 Oct 2020 12:41:13

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
User closed query 'PV Query: Please confirm if liver laceration was grade IV (per event term) or grade V per event narrative' (Site from Safety).	(b) (4), (b) (6)	25 Nov 2020 19:02:20
Query 'PV Query: Please confirm if liver laceration was grade IV (per event term) or grade V per event narrative' answered with 'This was updated to Grade IV' (Site from Safety).	Steven Anderson (b) (4)	24 Nov 2020 19:46:39
User opened query 'PV Query: Please confirm if liver laceration was grade IV (per event term) or grade V per event narrative' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:39:35
DataPoint Verified.		22 Oct 2020 18:33:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLG: Injuries NEC, HLT: Abdominal and gastrointestinal injuries NEC, PT: Traumatic liver injury, LLT: Liver laceration - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 21:59:33
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4)	19 Oct 2020 21:59:33
Data point term sent to Coder	System	19 Oct 2020 21:03:04
User entered 'GRADE IV LIVER LACERATION'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 21:02:23
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:28:48
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	06 Apr 2021 20:28:48
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User closed 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. Please do not reply to this query until the information is obtained. ' (Site from Safety).		07 Apr 2021 14:26:03
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. Please do not reply to this query until the information is obtained. ' answered with 'updated' (Site from Safety).	Andrea Newlands (b) (4)	06 Apr 2021 20:28:55
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:28:48
User entered '28 Jan 2021' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:28:48
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. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:28:22
User closed 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. Please do not reply to this query until the information is obtained. ' (Site from Safety).		11 Nov 2020 19:06:09
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. Please do not reply to this query until the information is obtained. ' answered with 'Site will not leave these open any longer. please see other queries on why' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:44:06

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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. Please do not reply to this query until the information is obtained. ' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:16:45
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 21:02:23
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[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. Please do not reply to this query until the information is obtained. ' canceled (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:28:24
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. Please do not reply to this query until the information is obtained. ' (Site from Safety).		19 Nov 2020 21:35:46
User entered empty.	System	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'I'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 04:56:13
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:29:09
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:29:09
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 21:02:23
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
User closed query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	11 Nov 2020 10:14:43
Query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' answered with 'blood transfusion was the medical treatment for the liver laceration' (Site from DM).	Steven Anderson (b) (4)	10 Nov 2020 22:53:04
User opened query 'Per DM CLR: Other Action Taken = ConProc. However, there is no recorded Concomitant Procedure that match this AE during this time frame. Please update to record the therapeutic procedure for this AE as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	28 Oct 2020 15:09:14
DataPoint Verified.	(b) (4)	22 Oct 2020 18:33:49
User entered 'I'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
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. Please do not reply to this query until the event information has been obtained.' (Site from Safety). 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. Please do not reply to this query until the event information has been obtained.' answered with 'updated' (Site from Safety).		07 Apr 2021 14:26:10
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:28:58
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:28:48
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. Please do not reply to this query until the event information has been obtained.' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:35:59
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. Please do not reply to this query until the event information has been obtained.' (Site from Safety). 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. Please do not reply to this query until the event information has been obtained.' answered with 'Site will no longer leave these queries open. please see other queries on why.' (Site from Safety).		11 Nov 2020 19:06:24
	Steven Anderson (b) (4)	10 Nov 2020 22:44:29

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
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. Please do not reply to this query until the event information has been obtained.' (Site from Safety). DataPoint Verified.	(b) (4), (b) (6)	23 Oct 2020 12:16:27
		22 Oct 2020 18:33:49
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	19 Oct 2020 21:02:23
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'SUBJECT WAS IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Serious Adverse Event Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (9)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 21:02:23

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
Reviewed for Safety.		20 Oct 2020 12:42:53
User entered 'USA-US061-2020-mRNA-1273-P301000005'		20 Oct 2020 12:42:49

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User coded data point as SOC: Blood and lymphatic system disorders, HLGT: Anaemias nonhaemolytic and marrow depression, HLT: Anaemias NEC, PT: Blood loss anaemia, LLT: Acute post hemorrhagic anemia - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:08:28
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Oct 2020 21:08:28
Data point term sent to Coder	System	19 Oct 2020 21:07:09
User entered 'ACUTE POST HEMORRHAGIC ANEMIA'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
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. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:28:32
User closed 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. Please do not reply to this query until the information is obtained.' (Site from Safety).		11 Nov 2020 19:07:09
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. Please do not reply to this query until the information is obtained.' answered with 'Site will not leave this open please refer to other queries on why' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:53:37
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. Please do not reply to this query until the information is obtained.' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:11:28
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

End time (00:00-23:59)

Audit	User	Time (GMT)
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. Please do not reply to this query until the event information has been obtained. ' canceled (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:29:46
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. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).		19 Nov 2020 21:29:35
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[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. Please do not reply to this query until the information is obtained.' canceled (Site from Safety).	(b) (4), (b) (6)	21 Dec 2020 22:28:33
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. Please do not reply to this query until the information is obtained.' (Site from Safety).		19 Nov 2020 21:30:02
User entered empty.	System	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Grade 4 (Grade 4)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'I'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '08 Sep 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '10'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 00:13:26
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:29:54
User entered 'Not Applicable (NOT APPLICABLE)'	(b) (4)	22 Oct 2020 21:29:54
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	19 Oct 2020 21:07:04
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[None](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '1'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
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. Please do not reply to this query until the event information has been obtained. ' (Site from Safety).	(b) (4), (b) (6)	19 Nov 2020 21:30:25
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. Please do not reply to this query until the event information has been obtained' (Site from Safety).		11 Nov 2020 19:07:17
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. Please do not reply to this query until the event information has been obtained' answered with 'site will not leave these open anymore please see other queries on why' (Site from Safety).	Steven Anderson (b) (4)	10 Nov 2020 22:53:54
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. Please do not reply to this query until the event information has been obtained' (Site from Safety).	(b) (4), (b) (6)	23 Oct 2020 12:11:15
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Recovering/Resolving (RECOVERING/RESOLVING)'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

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Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'SUBJECT WAS INVOLVED IN MOTOR VEHICLE ACCIDENT'	Mylene Asmar-Rios (b) (4)	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (10)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Oct 2020 21:07:04

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User coded data point as SOC: Injury, poisoning and procedural complications, HLGT: Bone and joint injuries, HLT: Limb fractures and dislocations, PT: Lower limb fracture, LLT: Lower limb fracture - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 09:21:31
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 09:21:31
Data point term sent to Coder	System	21 Oct 2020 16:49:07
User entered 'Right Tib/ Fib Fracture'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		10 Nov 2020 00:09:09
User closed query 'Please clarify - this was injury from MVA not after so start date should be 8 Sep 2020? Repair was 13 Sep 2020' (Site from CRA).		10 Nov 2020 00:09:06
Query 'Please clarify - this was injury from MVA not after so start date should be 8 Sep 2020? Repair was 13 Sep 2020' answered with 'As per hospital discharge papers this was actually found incidentally and might be age related ' (Site from CRA).	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:21:27
User opened query 'Please clarify - this was injury from MVA not after so start date should be 8 Sep 2020? Repair was 13 Sep 2020' (Site from CRA).	(b) (4), (b) (6)	22 Oct 2020 18:50:22
DataPoint Un-verified.		22 Oct 2020 18:47:14
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
User entered empty.	System	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		16 Apr 2021 18:25:35
User closed query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).		07 Apr 2021 18:41:56
Query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 20:29:51
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 20:29:45
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 20:29:45
User opened query 'Per DM CLR: Please review the status of this AE and verify if this already resolved and end date is already available. If yes, please update eCRF as appropriate. Otherwise, confirm if it is still ongoing. ' (Site from DM).	(b) (4), (b) (6)	29 Nov 2020 09:23:24
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		16 Apr 2021 18:25:35
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:29:45
User entered '24 Feb 2021' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 20:29:45
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios	21 Oct 2020 16:48:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
User entered empty.	System	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

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Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		10 Nov 2020 00:13:42
DataPoint Un-verified.	Mylene Asmar-Rios	22 Oct 2020 21:22:38
	(b) (4)	
User entered 'Not Applicable (NOT APPLICABLE)'	Mylene Asmar-Rios	22 Oct 2020 21:22:38
reason for change: Data Entry Error	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered 'None (NONE)'	Mylene Asmar-Rios	21 Oct 2020 16:48:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'I'	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.		16 Apr 2021 18:25:35
User closed query 'Per CDM: Per sponsor review, please review outcome. ' (Site from DM).		07 Apr 2021 18:42:08
Query 'Per CDM: Per sponsor review, please review outcome. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	06 Apr 2021 20:29:57
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 20:29:45
	(b) (4)	
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	Andrea Newlands (b) (4)	06 Apr 2021 20:29:45
Data Entry Error	(b) (4)	
User opened query 'Per CDM: Per sponsor review, please review outcome. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:39:10
DataPoint Verified.		22 Oct 2020 18:33:49
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios	21 Oct 2020 16:48:10
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

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 20:32:11
DataPoint Verified.		22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
DataPoint Verified.	(b) (4), (b) (6)	22 Oct 2020 18:33:49
User entered empty.	Mylene Asmar-Rios (b) (4)	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
User entered '0'	System	21 Oct 2020 16:48:10

US3412125

Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11
User entered 'I'	System	21 Oct 2020 16:48:10

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Folder: Adverse Events

Form: Adverse Events (11)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:11

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16

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Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		13 Feb 2021 16:33:00
User closed query 'Please correct spelling' (Site from CRA).		13 Feb 2021 16:32:58
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 14:06:46
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	12 Feb 2021 14:06:46
Data point term sent to Coder	System	12 Feb 2021 14:06:28
Query 'Please correct spelling' answered with 'updated' (Site from CRA).	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 14:05:38
Coding entries removed.	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 14:05:34
User entered 'hyperglycemia' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 14:05:34
User opened query 'Please correct spelling' (Site from CRA).	(b) (4), (b) (6) (b) (4)	29 Dec 2020 20:29:35
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Glucose metabolism disorders (incl diabetes mellitus), HLT: Hyperglycaemic conditions NEC, PT: Hyperglycaemia, LLT: Hyperglycemia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:52:19
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:52:19
Data point term sent to Coder	System	22 Oct 2020 21:34:06
User entered 'HRYPEGLYCEMUA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:01
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:05
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:07
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:10
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:12
User entered empty.	Mylene Asmar-Rios	22 Oct 2020 21:33:52
	(b) (4)	

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
User entered empty.	System	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:30:45
DataPoint Un-verified.	(b) (4), (b) (6)	29 Dec 2020 20:30:20
DataPoint Verified.	(b) (4), (b) (6)	29 Dec 2020 20:30:14
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		16 Apr 2021 18:25:35
User entered '09 Dec 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:30:45
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		16 Apr 2021 18:25:35
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
User entered empty.	System	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:25
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:27
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:36
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:37
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:39
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:42
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:43
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:46
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:49
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:50
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:52
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:55
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:56
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:30:58
User entered 'Not Applicable (NOT APPLICABLE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[None](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:31:00
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:31:02
User entered 'I'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		29 Dec 2020 20:31:04
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		16 Apr 2021 18:25:35
User closed query 'Per CDM: Per sponsor review, please confirm Outcome is unknown.' (Site from DM).		07 Apr 2021 18:42:45
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:30:45
Query 'Per CDM: Per sponsor review, please confirm Outcome is unknown.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	06 Apr 2021 20:30:40
User opened query 'Per CDM: Per sponsor review, please confirm Outcome is unknown.' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:39:47
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

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 20:32:16
DataPoint Verified.		16 Apr 2021 18:25:35
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
DataPoint Verified.		16 Apr 2021 18:25:35
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
User entered '0'	System	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16
User entered 'I'	System	22 Oct 2020 21:33:52

US3412125

Folder: Adverse Events

Form: Adverse Events (12)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:16

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:20
User coded data point as SOC: Metabolism and nutrition disorders, HLG: Electrolyte and fluid balance conditions, HLT: Sodium imbalance, PT: Hyponatraemia, LLT: Hyponatremia - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:41:26
User coded data point as Term Coded data point by User: Coder System - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:41:26
Data point term sent to Coder	System	22 Oct 2020 21:40:24
User entered 'HYPONATREMIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:24
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:25
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:28
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:30
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

Start time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:31
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
User entered empty.	System	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		16 Apr 2021 18:25:35
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:31:12
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		16 Apr 2021 18:25:35
User entered '09 Dec 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:31:12
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[End time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
User entered empty.	System	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:40
User entered 'Grade 2/Moderate (Grade 2/Moderate)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:41
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:44
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:46
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:49
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:51
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:53
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:55
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:33:57
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:34:00
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:34:01
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:34:03
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:34:06
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:34:08
User entered 'Not Related (NOT RELATED)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

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[Action taken with investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:34:10
User entered 'Not Applicable (NOT APPLICABLE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

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Folder: Adverse Events

Form: Adverse Events (13)

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None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:34:23
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:34:29
User entered 'I'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

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[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:34:30
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

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[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		16 Apr 2021 18:25:35
User closed query 'Per CDM: Per sponsor review, please confirm outcome. ' (Site from DM).		07 Apr 2021 18:42:55
Query 'Per CDM: Per sponsor review, please confirm outcome. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	06 Apr 2021 20:31:17
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)' reason for change:	(b) (4)	
Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:31:12
User opened query 'Per CDM: Per sponsor review, please confirm outcome. ' (Site from DM).	(b) (4), (b) (6)	30 Mar 2021 15:40:13
User entered 'Unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

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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 20:32:21
DataPoint Verified.		16 Apr 2021 18:25:35
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

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[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
DataPoint Verified.		29 Dec 2020 20:34:33
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 21:40:13

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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 20:32:21
User entered '0'	System	22 Oct 2020 21:40:13

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Folder: Adverse Events

Form: Adverse Events (13)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:21
User entered 'I'	System	22 Oct 2020 21:40:13

US3412125

Folder: Adverse Events

Form: Adverse Events (13)

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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 20:32:21

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Folder: Adverse Events

Form: Adverse Events (14)

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[AEID](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
Reviewed for Safety.		07 Apr 2021 14:48:05
User entered 'USA-US061-2020-mRNA-1273-P301000005'		07 Apr 2021 14:45:50
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 22:54:17

US3412125

Folder: Adverse Events

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[Adverse event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User coded data point as SOC: Nervous system disorders, HLGT: Central nervous system vascular disorders, HLT: Central nervous system haemorrhages and cerebrovascular accidents, PT: Subarachnoid haemorrhage, LLT: Subarachnoid hemorrhage - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 22:55:18
User coded data point as Term Coded data point by User: (b) (6) - version MedDRA\23.0.	Coder Import (b) (4) (b) (4)	24 Feb 2021 22:55:18
Data point term sent to Coder	System	19 Feb 2021 19:15:23
User entered 'subarachnoid hemhorrhage'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 22:54:17

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Folder: Adverse Events

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[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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Folder: Adverse Events

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Start date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '23 Sep 2020'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17
	(b) (4)	

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Start time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 22:54:17

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[Ongoing?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '01 Oct 2020'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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End time (00:00-23:59)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 22:54:17

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[Severity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'Grade 4 (Grade 4)'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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Folder: Adverse Events

Form: Adverse Events (14)

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[Is the adverse event serious?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User closed query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	19 Feb 2021 19:16:10
Query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' answered by data change (Site from System).	System	19 Feb 2021 19:16:10
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:16:10
User opened query 'AE severity is Grade 4, but is the adverse event serious is No. Please confirm or correct.' (Site from System).	System	19 Feb 2021 19:15:15
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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Folder: Adverse Events

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[Death](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	(b) (4) Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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[Life threatening](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '1' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:16:10
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '08 Sep 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:16:10
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17
	(b) (4)	

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Hospital Discharge Date (dd MMM yyyy)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '01 Oct 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:16:10
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17
	(b) (4)	

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[Admitted to ICU?](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:16:10
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17
	(b) (4)	

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '10' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:16:49
User entered '1' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:16:10
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17
	(b) (4)	

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[Other medically important event](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17
	(b) (4)	

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[Relationship to investigational product](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'Not Related (NOT RELATED)'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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Action taken with investigational product

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:58:26
User closed query 'SUBARACHNOID HEMHORRAGE PV Query As the last dose of mRNA-1273 was given on 01 Sep 2020, please update the action taken from none to not applicable.' (Site from Safety).		20 Apr 2021 14:41:56
Query 'SUBARACHNOID HEMHORRAGE PV Query As the last dose of mRNA-1273 was given on 01 Sep 2020, please update the action taken from none to not applicable.' answered with 'this has been updated per query' (Site from Safety).	Steven Anderson (b) (4) (b) (4)	19 Apr 2021 14:05:51
User entered 'Not Applicable (NOT APPLICABLE)' reason for change: Data Entry Error	Steven Anderson (b) (4) (b) (4)	19 Apr 2021 14:05:27
DataPoint Un-verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:49
DataPoint Verified.		16 Apr 2021 18:25:35
User opened query 'SUBARACHNOID HEMHORRAGE PV Query As the last dose of mRNA-1273 was given on 01 Sep 2020, please update the action taken from none to not applicable.' (Site from Safety).		16 Apr 2021 14:33:12
User entered 'None (NONE)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 22:54:17

US3412125

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:32:44

None

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User closed query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).		07 Apr 2021 18:40:02
Query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	06 Apr 2021 20:41:30
User entered '0' reason for change: Data Entry Error	(b) (4)	06 Apr 2021 20:41:18
User opened query 'Per DM CLR: Other Action Taken = Concomitant Medication, however there is no Concomitant Medication recorded that matches this AE (verbatim) during this timeframe. Note that AE term and CM indication should be verbatim. Please review and add a Con Medication as appropriate or update action taken.' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:18:06
User entered '1'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User closed query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate' (Site from DM).		07 Apr 2021 18:40:04
Query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4)	06 Apr 2021 20:41:33
User entered '1' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:41:18
User opened query 'Per DM CLR: Please review and verify if this field should be ticked as there is a ConProc recorded that machth this AE during this timeframe. Review and update eCRF as appropriate' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 08:18:00
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	(b) (4)	
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:32:44

If outcome is Recovered/Resolved with Sequelae, please specify the sequelae:

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17

US3412125

Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
DataPoint Verified.	(b) (4), (b) (6)	20 Apr 2021 16:58:39
User closed query 'SUBARACHNOID HEMHORRAGE PV Query: Please provide treatment given for the event including medical intervention and/or surgical treatments. Please add any treatment medications to the concomitant medication eCRF (including dates of administration, dose, units, frequency, route and indication). If no treatment was provided, please state so.' (Site from Safety).		20 Apr 2021 14:42:12
Query 'SUBARACHNOID HEMHORRAGE 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 'this information has been input per hospital discharge summary. All information site has was input and all con procedures were added to con procedure form' (Site from Safety).	Steven Anderson (b) (4)	19 Apr 2021 14:25:47
DataPoint Un-verified.	(b) (4)	
	Steven Anderson (b) (4)	19 Apr 2021 14:24:46
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
User entered '71 YOF HISTORY OF OPEN SUBTOTAL COLECTOMY WITH END ILEOSTOMY S/P REVERSAL WITH LOWER MIDLINE INCISIONAL HERNIA S/P LAPAROSCOPIC REPAIR WITH MESH WHO PRESENTS S/P MVC ON SEP 8,2020 WITH MULTIPLE INJURIES INCLUDING SUBARACHNOID HEMORRHAGE, BLUNT CEREBROVASCULAR INJURY WITH SUBSEQUENT STROKE AND SEIZURE, GRADE IV LIVER LACERATION, AND RIGHT TIBIAL AND FIBULAR FRACTURES. GIVEN HER ANTICIPATED PROLONGED NEED FOR VENTILATORY SUPPORT AND ENTERAL NUTRITION A TRACHEOSTOMY AND PEG WERE PERFORMED. OF NOTE, THE PATIENT ALSO HAS AN EXTENSIVE ABDOMINAL SURGICAL HISTORY INCLUDING SUBTOTAL COLECTOMY WITH ILEORECTAL ANASTOMOSIS AND SUBSEQUENT VENTRAL HERNIA REPAIR WITH PERMANENT MESH.'	Steven Anderson (b) (4)	19 Apr 2021 14:24:46
reason for change: Data Entry Error DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User opened query 'SUBARACHNOID HEMHORRAGE 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).		16 Apr 2021 14:33:36
User closed query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Feb 2021 19:17:07
Query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' answered by data change (Site from System).	System	19 Feb 2021 19:17:07
User entered 'subject was in a motor vehicle accident' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:17:07

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EAB) (1725)

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
User opened query 'AE Serious is Yes but SAE Narrative is missing. Please provide.' (Site from System).	System	19 Feb 2021 19:16:10
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 19:10:50
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4)	10 Nov 2020 22:54:17
	(b) (4)	

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:32:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered '1'	System	19 Feb 2021 19:16:10
User entered '0'	System	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 22:54:17

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:32:44

Medically Attended AE Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
User entered 'I'	System	19 Feb 2021 19:15:15
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 22:54:17

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Folder: Adverse Events

Form: Adverse Events (14)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	19 Feb 2021 19:16:10
DataPoint activated with code reason code Data required.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:10:50
DataPoint inactivated with code reason code Data not required.	Steven Anderson (b) (4) (b) (4)	10 Nov 2020 22:54:17

US3412125

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[AEID](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Adverse event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User coded data point as SOC: Nervous system disorders, HLGT: Seizures (incl subtypes), HLT: Seizures and seizure disorders NEC, PT: Seizure, LLT: Seizure - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 19:19:55
User coded data point as Term Coded data point by User: Coder System - version MedDRA\\23.0.	Coder Import (b) (4) (b) (4)	19 Feb 2021 19:19:55
Data point term sent to Coder	System	19 Feb 2021 19:19:31
User entered 'seizure'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Was this a medically-attended AE?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'Yes (Y)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Was this a Solicited Adverse Reaction?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Is this event a confirmed diagnosis of Symptomatic Covid-19?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

Start date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered '08 Sep 2020'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Start time \(00:00-23:59\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[AE start date and time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
User entered empty.	System	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, end date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered '08 Sep 2020'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

End time (00:00-23:59)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[AE End Date and Time \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
User entered empty.	System	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Severity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered 'Grade 1/Mild (Grade 1/Mild)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Is the adverse event serious?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

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[Death](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

Hospital Admission Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

Hospital Discharge Date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

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[Number of Days in ICU](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

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[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

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[Other medically important event](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

US3412125

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Relationship to investigational product](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.	(b) (4), (b) (6)	16 Apr 2021 18:25:35
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 19:19:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 19:19:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:19:38
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 19:19:28
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Relationship to Study Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 19:19:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 19:19:38
User entered 'Not Related (NOT RELATED)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:19:38
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 19:19:28
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

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Action taken with investigational product

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User closed query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 19:19:38
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	19 Feb 2021 19:19:38
User entered 'None (NONE)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:19:38
User opened query 'Data is required. Please complete.' (Site from System).	System	19 Feb 2021 19:19:28
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

None

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

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[Concomitant Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered 'I'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Concomitant Procedure](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered '0'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Outcome](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered 'Recovered/Resolved (RECOVERED/RESOLVED)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

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Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

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 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered empty.	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

US3412125

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Narrative](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
DataPoint Verified.		16 Apr 2021 18:25:35
User entered 'subject experience generalized tonic clinic seizure activity which was resolved with lorazepam and keppra'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:19:28

US3412125

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

Serious Adverse Event Derived (CSA Programming Field Only)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
User entered '0'	System	19 Feb 2021 19:19:28

US3412125

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Medically Attended AE Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27
User entered '1'	System	19 Feb 2021 19:19:28

US3412125

Folder: Adverse Events

Form: Adverse Events (15)

Generated On: 09 Jun 2021 17:32:44

[Admitted to ICU Derived \(CSA Programming Field Only\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	30 Apr 2021 20:32:27

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:31
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:56
User closed query 'Per DM CLR: Per Diary Dose 2 Day 1-2, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 07:53:53
Query 'Per DM CLR: Per Diary Dose 2 Day 1-2, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' answered with 'subject error. none taken' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 20:06:51
User opened query 'Per DM CLR: Per Diary Dose 2 Day 1-2, Pain at Injection Site = Any use of prescription pain reliever or prevents daily activity, however, there is no corresponding Conmed recorded that matches this information in the ConMed eCRF page. Please reconcile and update to record the medication given as appropriate, otherwise clarify. ' (Site from DM).	(b) (4), (b) (6)	17 Feb 2021 18:11:07
User closed query 'Per CDM: Diary Dose 2, Log Line #5 e-diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' (Site from DM).		27 Oct 2020 12:13:44

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination Summary

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Query 'Per CDM: Diary Dose 2, Log Line #5 e-diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. ' answered with 'metamucil was taken for this and has been recorded in concomitant medications' (Site from DM).	Jacob sekinger (b) (4)	20 Oct 2020 14:53:42
User opened query 'Per CDM: Diary Dose 2, Log Line #5 e-diary reports medication was taken for PAIN or FEVER, however there is no corresponding medication recorded. Please confirm if medication was taken and update the Concomitant Medications page with details of the medication taken as appropriate, or if medication is already recorded, please provide log line number. (Site from DM).	(b) (4), (b) (6)	14 Oct 2020 10:03:18
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4), (b) (6)	21 Aug 2020 15:41:46
User entered 'No (N)'	Steven Anderson (b) (4)	11 Aug 2020 13:03:37
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:44:19
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:44:19
Data point term sent to Coder	System	21 Aug 2020 15:42:57
User entered 'AMLODIPINE'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPERTENSION'		21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered '5'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'		21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2019'		21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'		21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 20:43:43
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:43:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'		21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 20:43:43
	(b) (4)	
User entered '19 Nov 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:43:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User entered '1'	System	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User entered '1'	System	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (1)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:04:38
User entered '804 (804)'	System	21 Aug 2020 15:42:19

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: ATENOLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:44:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:44:18
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:43:00
User entered 'ATENOLOL'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPERTENSION'		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
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).		27 Oct 2020 12:15:32
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 'per patient records, this is the correct dosage.' (Site from DM).	Jacob sekinger (b) (4)	26 Oct 2020 18:28:33
	(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)	23 Oct 2020 11:23:05
User entered '35'		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2019'		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (2)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:42:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: OTHER CENTRALLY ACTING AGENTS, PRODUCT: CYCLOBENZAPRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 15:42:22
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Aug 2020 15:42:22
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:44:03
User entered 'CYCLOBENZAPRINE'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'CHRONIC LOW BACK PAIN'		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered '5'	(b) (4), (b) (6)	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'as needed (PRN)'		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User closed query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).		10 Nov 2020 06:03:28
Query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' answered with 'MH has been updated' (Site from DM).	Mylene Asmar-Rios (b) (4)	05 Nov 2020 20:56:37
User opened query 'Per DM CLR: Con Med start date is prior to the start date of the corresponding MH condition. Please review and reconcile Con Med and MH start dates as appropriate. Otherwise, clarify.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:24:18
User entered 'UN UNK 2009'		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (3)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:43:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: DRUGS FOR FUNCTIONAL GASTROINTESTINAL DISORDERS, ATC: SYNTHETIC ANTICHOLINERGICS, ESTERS WITH TERTIARY AMINO GROUP, PRODUCT: DICYCLOVERINE HYDROCHLORIDE, PRODUCTSYNONYM: DICYCLOMINE HYDROCHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:45:18
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:45:18
Data point term sent to Coder	System	21 Aug 2020 15:45:07
User entered 'DICYCLOMINE HYDROCHLORIDE'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'IRRITABLE BOWEL SYNDROME-D'		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered '20'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	(b) (4), (b) (6)	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'as needed (PRN)'		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2000'		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (4)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	21 Aug 2020 15:44:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:45:46
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	21 Aug 2020 15:45:46
Data point term sent to Coder	System	21 Aug 2020 15:45:08
User entered 'LEVOTHYROXINE'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered 'HYPOTHYROID'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '75'		21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'ug (ug)'		21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'		21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2010'		21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered '0'	(b) (4), (b) (6)	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 20:44:13
	(b) (4)	
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:44:13
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'		21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 20:44:13
	(b) (4)	
User entered '03 Nov 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:44:13
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User entered '1'	System	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User entered '1'	System	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (5)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:27
User entered '804 (804)'	System	21 Aug 2020 15:44:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: AGENTS ACTING ON THE RENIN-ANGIOTENSIN SYSTEM, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, ATC: ANGIOTENSIN II RECEPTOR BLOCKERS (ARBS), PLAIN, PRODUCT: LOSARTAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:47:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:47:18
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:46:08
User entered 'LOSARTAN'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPERTENSION'		21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '100'		21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'		21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'		21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered 'UN UNK 2019'	(b) (4), (b) (6)	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'		21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'		21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (6)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:45:23

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, ATC: ANTIINFLAMMATORY AND ANTIRHEUMATIC PRODUCTS, NON-STEROIDS, ATC: OXICAMS, PRODUCT: MELOXICAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:47:18
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:47:18
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:46:09
User entered 'MELOXICAM'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'OSTEOARTHRITIS'		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '15'		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	(b) (4), (b) (6)	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[If route of administration is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2019'		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (7)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:45:57

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: NASAL DECONGESTANTS FOR SYSTEMIC USE, ATC: SYMPATHOMIMETICS, PRODUCT: PSEUDOEPHEDRINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 07:34:51
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	01 Sep 2020 07:34:51
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:47:15
User entered 'PSEUOBEPHEDRINE'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	10 Nov 2020 21:57:34
User entered 'No (N)'	(b) (4), (b) (6)	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'SEROUS OTITIS MEDIA'		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '120'		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2000'		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (8)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:46:51

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: VITAMIN A AND D, INCL. COMBINATIONS OF THE TWO, ATC: VITAMIN D AND ANALOGUES, PRODUCT: VITAMIN D NOS, PRODUCTSYNONYM: VITAMIN D [VITAMIN D NOS] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:49:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:49:22
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:48:23
User entered 'VITAMIN D'	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'GENERAL HEALTH'		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 12:14:28
		10 Nov 2020 21:57:34
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'THIS IS AN OTC MEDICATION AND PATIENT DOES NOT KNOW DOSAGE' (Site from DM).	Melissa Fuson (b) (4)	10 Nov 2020 20:31:26
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:25:19
User entered 'I'		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'capsule (CAPSULE)'		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '5 Aug 2020'		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	(b) (4), (b) (6)	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (9)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:47:28

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: CALCIUM, ATC: CALCIUM, PRODUCT: CALCIUM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:49:22
	(b) (4)	
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	21 Aug 2020 15:49:22
	(b) (4)	
Data point term sent to Coder	System	21 Aug 2020 15:48:23
User entered 'CALCIUM'	(b) (4), (b) (6)	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'GENERAL HEALTH'		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM). DataPoint Verified.	(b) (4), (b) (6)	11 Nov 2020 12:16:07
		10 Nov 2020 21:57:34
Query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' answered with 'THIS IS AN OTC MEDICATION AND PATIENT DOES NOT KNOW DOSAGE' (Site from DM).	Melissa Fuson (b) (4)	10 Nov 2020 20:31:36
User opened query 'Per DM CLR: Please provide the actual dose for this medication instead of tablet count, as there are multiple dosage options for this drug. Update the Dose and Dose Unit fields as appropriate.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:23:47
User entered 'I'		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'capsule (CAPSULE)'		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '5 Aug 2020'		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'		21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (10)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	21 Aug 2020 15:47:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
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)	22 Sep 2020 13:05:35
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Sep 2020 13:05:35
Data point term sent to Coder	System	22 Sep 2020 13:04:22
User entered 'Tylenol' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:31
Data point term sent to Coder	System	22 Sep 2020 13:03:20
User entered 'Ty;emp;'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'OA'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '500'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'as needed (PRN)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'un UNK 2019'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Un-verified.	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 20:44:56
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 20:44:56
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Melissa Fuson (b) (4)	22 Sep 2020 13:03:05
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:44:56
User entered '01 Oct 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:44:56
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User entered empty.	System	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User entered empty.	System	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (11)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:34
User entered empty.	System	22 Sep 2020 13:03:05

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: BULK-FORMING LAXATIVES, PRODUCT: PLANTAGO OVATA, PRODUCTSYNONYM: METAMUCIL [PLANTAGO OVATA] - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:22:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	24 Sep 2020 00:22:47
Data point term sent to Coder	System	22 Sep 2020 13:36:12
User entered 'Metamucial'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'IBS'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'I'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Per DM CLR: Please review if the number of PACKETS/SACHET would be a more appropriate dose and unit instead of the number of glass. Update as appropriate. Otherwise, provide clarification.' (Site from DM). DataPoint Verified.	(b) (4) (b) (4), (b) (6)	11 Nov 2020 12:17:42
		10 Nov 2020 21:57:34
Query 'Per DM CLR: Please review if the number of PACKETS/SACHET would be a more appropriate dose and unit instead of the number of glass. Update as appropriate. Otherwise, provide clarification.' answered with 'UPDATED TO ADD SACHET' (Site from DM).	Melissa Fuson (b) (4) (b) (4)	10 Nov 2020 20:34:01
User entered 'EIGHT OUNCE GLASS WITH SACHET' reason for change: Data Entry Error	Melissa Fuson (b) (4) (b) (4)	10 Nov 2020 20:33:46
User opened query 'Per DM CLR: Please review if the number of PACKETS/SACHET would be a more appropriate dose and unit instead of the number of glass. Update as appropriate. Otherwise, provide clarification.' (Site from DM).	(b) (4), (b) (6)	23 Oct 2020 11:24:43
User entered 'Eight ounce glass'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'I'	(b) (4)	
	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
	(b) (4)	
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
	(b) (4)	
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4) (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Melissa Fuson (b) (4)	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	(b) (4) Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (12)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Sep 2020 13:35:32
DataPoint activated with code reason code Data required.	Melissa Fuson (b) (4)	22 Sep 2020 13:33:41
DataPoint inactivated with code reason code Data not required.	Melissa Fuson (b) (4)	22 Sep 2020 13:06:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTI-PARKINSON DRUGS, ATC: DOPAMINERGIC AGENTS, ATC: ADAMANTANE DERIVATIVES, PRODUCT: AMANTADINE HYDROCHLORIDE, PRODUCTSYNONYM: AMANTADINE HCL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 21:30:24
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 Oct 2020 21:30:24
Data point term sent to Coder	System	22 Oct 2020 14:16:02
User entered 'AMANTADINE HCL'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	19 Feb 2021 19:26:43
	(b) (4)	
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	19 Feb 2021 19:26:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios	22 Oct 2020 14:15:24
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'TRAUMATIC BRAIN INJURY'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4) (b) (4), (b) (6)	15 Feb 2021 11:03:29
Query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 13:27:22
DataPoint Un-verified.	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 13:27:14
User entered '50' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	12 Feb 2021 13:27:14
User opened query 'Per DM CLR: Please review the dosage as this is not the expected dosage for this medication. Please review and either correct dosage or provide explanation for alternate dosage of this medication. Please update eCRF as appropriate.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 21:01:12
DataPoint Verified.		10 Nov 2020 21:57:34
User entered '50/5'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'PER GASTRIC TUBE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 14:22:33
Query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' answered with 'conmed is used as prophylaxis as result of brain injury to prevent future issues.' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:26:37
User opened query 'Per DM CLR: The Con Med continues after the resolution date of the corresponding Adverse Event. Please review and reconcile ConMed and Adverse Event start/stop dates as appropriate or provide explanation for why Con Med continued after the AE had resolved.' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 21:01:04
DataPoint Verified.		10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (13)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:15:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 14:55:37
	(b) (4)	
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 14:55:37
	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 14:18:04
User entered 'APIRABAN'	Mylene Asmar-Rios	22 Oct 2020 14:17:30
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'LEFT INTERCAROTID ARTERY DISSECTION WITH NTRALUMINAL THROMBUS'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '5'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'twice daily (BID)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (15)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:17:30

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: ALPHA AND BETA BLOCKING AGENTS, PRODUCT: CARVEDILOL, PRODUCTSYNONYM: CARVEDIOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 14:27:01
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 14:27:01
Data point term sent to Coder	System	22 Oct 2020 14:19:11
User entered 'CARVEDIOL'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. '(Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 07:53:26
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' answered with 'no, was begun during subject's hospital stay' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 19:55:51
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of HYPERTENSION worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. '(Site from DM).	(b) (4), (b) (6)	04 Jan 2021 21:01:24
DataPoint Verified.		10 Nov 2020 21:57:34
User entered 'HYPERTENSION'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '3.125'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'twice daily (BID)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (16)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:19:07

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GERD worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	22 Feb 2021 07:53:37
Query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GERD worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate.	Andrea Newlands (b) (4)	19 Feb 2021 19:55:57
' answered with 'no, was begun during subject's hospital stay' (Site from DM).	(b) (4)	
User opened query 'Per DM CLR: Please review if this medication was added because the patient's medical history of GERD worsened. If yes, please review if an AE reflecting worsening of corresponding MH condition should be recorded. Update all applicable eCRFs if appropriate. ' (Site from DM).	(b) (4), (b) (6)	04 Jan 2021 21:01:34
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
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: ESOMEPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:21:37
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:21:37
Data point term sent to Coder	System	22 Oct 2020 14:20:15
User entered 'ESOMEPRAZOLE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'GERD'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '40'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'PER GASTRIC TUBE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (17)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:20:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTIANEMIC PREPARATIONS, ATC: IRON PREPARATIONS, ATC: IRON BIVALENT, ORAL PREPARATIONS, PRODUCT: FERROUS SULFATE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	22 Oct 2020 14:27:08
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	(b) (4)	
Data point term sent to Coder	System	22 Oct 2020 14:21:15
User entered 'FERROUS SULFATE'	Mylene Asmar-Rios	22 Oct 2020 14:20:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'ANEMIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '325'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
DataPoint Un-verified.	Andrea Newlands (b) (4)	13 Apr 2021 19:45:43
	(b) (4)	
User entered '08 Sep 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 19:45:43
	(b) (4)	
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios	22 Oct 2020 14:20:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (18)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:20:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
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, LONG-ACTING, PRODUCT: INSULIN GLARGINE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:27:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:27:30
Data point term sent to Coder	System	22 Oct 2020 14:22:17
User entered 'INSULIN GLARGINE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPERGLYCEMIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '20'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'IU (IU)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:49:11
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:49:11
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Future date has been entered. Please correct.' (Site from System).	(b) (4)	
User entered '09 Dec 2020' reason for change: Data Entry Error	System	06 Apr 2021 20:49:25
User opened query 'Future date has been entered. Please correct.' (Site from System).	Andrea Newlands (b) (4)	06 Apr 2021 20:49:25
DataPoint Un-verified.	(b) (4)	
User entered '09 Dec 2021' reason for change: Data Entry Error	System	06 Apr 2021 20:49:11
DataPoint Verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:49:11
User entered empty.	(b) (4)	
	(b) (4), (b) (6)	10 Nov 2020 21:57:34
	Mylene Asmar-Rios	22 Oct 2020 14:21:48
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User entered '1'	System	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User entered '1'	System	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (19)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:51
User entered '804 (804)'	System	22 Oct 2020 14:21:48

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
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, PRODUCTSYNONYM: INSULIN, REGULAR - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:37:34
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 Oct 2020 15:37:34
Data point term sent to Coder	System	22 Oct 2020 14:24:25
User entered 'INSULIN REGULAR'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPERGLYCEMIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0-12'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'IU (IU)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'three times daily (TID)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Subcutaneous (SUBCUTANEOUS)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:49:37
User entered 'No (N)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:49:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Un-verified.	Andrea Newlands (b) (4)	06 Apr 2021 20:49:37
User entered '09 Dec 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	06 Apr 2021 20:49:37
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User entered '3'	System	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User entered '1'	System	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (20)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:05:58
User entered '804 (804)'	System	22 Oct 2020 14:24:24

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:27:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	25 Oct 2020 04:27:42
Data point term sent to Coder	System	22 Oct 2020 14:25:26
User entered 'SODIUM CHLORIDE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'HYPONATREMIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '2'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'g (g)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'three times daily (TID)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'PER NASOGASTRIC TUBE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Yes (Y)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (21)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	22 Oct 2020 14:25:25

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:34:31
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 Oct 2020 15:34:31
Data point term sent to Coder	System	22 Oct 2020 14:26:27
User entered 'PANTAPROZOLE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'GERD'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '40'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'mg (mg)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'once daily (QD)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Oral (ORAL)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UN UNK 2009'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '01 Oct 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User entered '1'	System	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User entered '1'	System	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (22)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:06:54
User entered '804 (804)'	System	22 Oct 2020 14:26:12

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
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)	22 Oct 2020 16:24:42
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 16:24:42
Data point term sent to Coder	System	22 Oct 2020 14:45:12
User entered 'VANCOMYCIN'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'MRSA PNEUMONIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNK'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNKNOWN'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNKNOWN'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '29 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User entered empty.	System	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User entered empty.	System	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (23)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:02
User entered empty.	System	22 Oct 2020 14:44:59

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User coded data point as ATC: ANTIINFECTIVES FOR SYSTEMIC USE, ATC: ANTIBACTERIALS FOR SYSTEMIC USE, ATC: OTHER BETA-LACTAM ANTIBACTERIALS, ATC: FOURTH-GENERATION CEPHALOSPORINS, PRODUCT: CEFEPIME - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	22 Oct 2020 15:03:36
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 Oct 2020 15:03:36
Data point term sent to Coder	System	22 Oct 2020 14:46:14
User entered 'CEFEPIME'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'MRSA PNEUMONIA'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNK'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNKOWN'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'unknown (UNKNOWN)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'Other (OTHER)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'UNKOWN'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '09 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '0'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered '29 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:57:34
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User entered empty.	System	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User entered empty.	System	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (24)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:10
User entered empty.	System	22 Oct 2020 14:46:09

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
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)	16 Feb 2021 11:36:56
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 11:36:56
Data point term sent to Coder	System	12 Feb 2021 14:33:53
Coding entries removed.	Andrea Newlands (b) (4)	12 Feb 2021 14:33:47
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)	17 Dec 2020 21:00:43
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	17 Dec 2020 21:00:43
Data point term sent to Coder	System	17 Dec 2020 16:20:12
Data point term sent to Coder	System	17 Dec 2020 16:18:11
User entered 'HEPARIN'	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'EMBOLIC INFARCT - MULTIPLE LEFT HEMISPHERic' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	12 Feb 2021 14:33:47
User entered 'EMBOLIC INFARCT - MULTIPLE LEFT HEMISPHERic'	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:19:31
User entered 'UNK' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 16:19:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Dec 2020 16:17:42
	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:19:31
User entered 'Other (OTHER)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 16:19:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Dec 2020 16:17:42
	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4)	
	Melissa Fuson (b) (4)	17 Dec 2020 16:19:31
User entered empty.	(b) (4)	
	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:19:31
User entered 'other (OTHER)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 16:19:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Dec 2020 16:17:42
	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'UNKNOWN' reason for change: Data Entry Error	(b) (4)	17 Dec 2020 16:19:31
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:19:31
User entered 'Intravenous (INTRAVENOUS)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 16:19:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Dec 2020 16:17:42
	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	(b) (4)	17 Dec 2020 16:19:31
User entered '01 Oct 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 16:19:31
User opened query 'Start date is missing and Start date completely unknown is not checked. Please provide.' (Site from System).	System	17 Dec 2020 16:17:42
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:19:31
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 16:19:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Dec 2020 16:17:42
	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '01 Oct 2020' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 16:19:31
User entered empty.	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Data is required. Please complete.' (Site from System).	(b) (4)	
Query 'Data is required. Please complete.' answered by data change (Site from System).	System	17 Dec 2020 16:19:31
User entered 'No (N)' reason for change: Data Entry Error	Melissa Fuson (b) (4)	17 Dec 2020 16:19:31
User opened query 'Data is required. Please complete.' (Site from System).	(b) (4)	
User entered empty.	System	17 Dec 2020 16:17:42
	Melissa Fuson (b) (4)	17 Dec 2020 16:17:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User entered empty.	System	17 Dec 2020 16:17:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User entered empty.	System	17 Dec 2020 16:17:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (25)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:28
User entered empty.	System	17 Dec 2020 16:17:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: OTHER ANTIEPILEPTICS, PRODUCT: LEVETIRACETAM, PRODUCTSYNONYM: KEPPRA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 22:02:57
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 Feb 2021 22:02:57
Data point term sent to Coder	System	19 Feb 2021 22:02:12
User entered 'keppra'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Per DM CLR: The indication signifies PREVENTION. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	07 Apr 2021 19:05:56
Query 'Per DM CLR: The indication signifies PREVENTION. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' answered with 'updated' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 20:50:32
User entered 'Yes (Y)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 20:50:27
User opened query 'Per DM CLR: The indication signifies PREVENTION. However, the response in this field reflects otherwise, Please review and update as appropriate. Else, provide justification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:56:48
Data hard unlocked.		01 Mar 2021 09:56:42
Data hard locked.		01 Mar 2021 09:56:37
User entered 'No (N)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'seizure prevention'	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unk'	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unk'	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unknown (UNKNOWN)'	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 22:08:20
User entered '08 Oct 2020'	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 20:50:56
User entered 'Yes (Y)'	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '15 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	06 Apr 2021 20:50:56
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User entered empty.	System	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User entered empty.	System	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (26)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:35
User entered empty.	System	19 Feb 2021 22:01:52

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: LORAZEPAM - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:15:51
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	20 Feb 2021 14:15:51
Data point term sent to Coder	System	19 Feb 2021 22:07:23
User entered 'lorazepam'	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'seizure'	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unk'	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unk'	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unknown (UNKNOWN)'	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 22:08:11
User entered '08 Oct 2020'	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '08 Sep 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 22:08:11
User entered '08 Oct 2020'	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User entered empty.	System	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User entered empty.	System	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (27)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:07:58
User entered empty.	System	19 Feb 2021 22:06:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOANALEPTICS, ATC: PSYCHOSTIMULANTS, AGENTS USED FOR ADHD AND NOOTROPICS, ATC: CENTRALLY ACTING SYMPATHOMIMETICS, PRODUCT: MODAFINIL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Mar 2021 07:43:02
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Mar 2021 07:43:02
Data point term sent to Coder	System	19 Feb 2021 22:08:23
User entered 'modafinil'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History/AE eCRF so there is an appropriate condition recorded' (Site from DM).	(b) (4) (b) (4), (b) (6)	12 Apr 2021 12:54:53
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History/AE eCRF so there is an appropriate condition recorded' answered with 'there is no underlying condition. the subject was put under anesthesia for surgery and was given modafinil to promote wakefulness.' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	06 Apr 2021 20:52:54
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History/AE eCRF so there is an appropriate condition recorded' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:57:56
Query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded		01 Mar 2021 09:57:44
' canceled (Site from DM).		
User opened query 'Per DM CLR: Please update the indication to reflect the underlying medical condition that this medication is being used to prevent/treat (not the drug class or action of drug). Please reconcile with Med History eCRF so there is an appropriate condition recorded		01 Mar 2021 09:57:22
' (Site from DM).		
User entered 'promote wakefulness'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unk'	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unk'	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unknown (UNKNOWN)'	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	(b) (4)	
	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '08 Sep 2020'	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '01 Oct 2020'	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User entered empty.	System	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User entered empty.	System	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (28)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:04
User entered empty.	System	19 Feb 2021 22:07:58

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	16 Apr 2021 10:59:22
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' answered with 'no ae, was used for management of hypertension while admitted to the hospital' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	13 Apr 2021 19:48:01
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 HYPERTENSION should be recorded, and update con med indication or provide clarification. ' (Site from DM).	(b) (4), (b) (6)	01 Mar 2021 09:58:26
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, ATC: BETA BLOCKING AGENTS, SELECTIVE, PRODUCT: METOPROLOL - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	19 Feb 2021 22:12:16
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 Feb 2021 22:12:16
Data point term sent to Coder	System	19 Feb 2021 22:11:30
User entered 'metoprolol'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'hypertension'	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unk'	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	(b) (4) System	19 Feb 2021 22:10:41
User entered 'Other (OTHER)' reason for change: Data Entry Error	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 22:10:41
User opened query 'Other, specify is provided, however Dose unit is not Other. Please correct.' (Site from System).	System	19 Feb 2021 22:10:34
User entered 'ug (ug)'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unk'	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'unknown (UNKNOWN)'	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'un Sep 2020'	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'UN Oct 2020' reason for change: Data Entry Error	(b) (4)	13 Apr 2021 19:48:52
User entered 'un Sep 2020'	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User entered empty.	System	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User entered empty.	System	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (29)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 05:37:05
User entered empty.	System	19 Feb 2021 22:10:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
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.	(b) (4) Coder Import (b) (4) (b) (4)	19 Feb 2021 22:15:57
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 Feb 2021 22:15:57
Data point term sent to Coder	System	19 Feb 2021 22:15:37
User entered 'tylenol'	Andrea Newlands (b) (4) (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN 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 of 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 did not meet the AE reporting criteria. ' (Site from DM).	(b) (4) (b) (4), (b) (6)	08 Mar 2021 04:32:11
Query 'Per DM CLR: Please note that there is no AE that matches this Con Med indication during this timeframe. If the INJECTION SITE PAIN 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 of 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 did not meet the AE reporting criteria. ' answered with 'did not meet reporting criteria' (Site from DM).	Andrea Newlands (b) (4) (b) (4)	05 Mar 2021 15:42:39

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '500'	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'mg (mg)'	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'once (ONCE)'	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '04 Sep 2020'	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '04 Sep 2020'	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User entered empty.	System	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User entered empty.	System	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (30)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:17
User entered empty.	System	19 Feb 2021 22:15:34

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: ANTITHROMBOTIC AGENTS, ATC: ANTITHROMBOTIC AGENTS, ATC: DIRECT FACTOR XA INHIBITORS, PRODUCT: APIXABAN, PRODUCTSYNONYM: ELIQUIS - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 15:01:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:01:48
Data point term sent to Coder	System	08 Apr 2021 15:01:13
User entered 'eliquis'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:01:11

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'thromboembolism prevention'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '5'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'twice daily (BID)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:11
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 15:01:11

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:01:11

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (31)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 15:01:11

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANTIEPILEPTICS, ATC: ANTIEPILEPTICS, ATC: BENZODIAZEPINE DERIVATIVES, PRODUCT: CLONAZEPAM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 15:02:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:02:57
Data point term sent to Coder	System	08 Apr 2021 15:02:15
User entered 'clonazepam'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:01:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'seizures'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0.5'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:01:45
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:01:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:01:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (32)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 15:01:45

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: CALCIUM CHANNEL BLOCKERS, ATC: SELECTIVE CALCIUM CHANNEL BLOCKERS WITH MAINLY VASCULAR EFFECTS, ATC: DIHYDROPYRIDINE DERIVATIVES, PRODUCT: AMLODIPINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 15:03:45
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:03:45
Data point term sent to Coder User entered 'amlodipine'	System Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:03:18 08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'hypertension'	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '10'	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '20 Nov 2020' reason for change: Data Entry Error	(b) (4)	
	Andrea Newlands (b) (4)	09 Apr 2021 16:24:34
User entered '19 Nov 2020'	(b) (4)	
	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '01 Jan 2021'	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User entered '1'	System	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User entered '1'	System	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (33)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:08:22
User entered '804 (804)'	System	08 Apr 2021 15:02:43

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
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, PRODUCTSYNONYM: VOLTAREN [DICLOFENAC] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	09 Apr 2021 05:53:30
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:53:30
Data point term sent to Coder	System	08 Apr 2021 15:07:23
User entered 'voltaren'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:07:01

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'motor vehicle accident'	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '4'	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'g (g)'	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'twice daily (BID)'	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Topical (TOPICAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '13 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:07:01
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 15:07:01

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:07:01

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (34)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 15:07:01

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

Name of Medication

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
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: ERGOCALCIFEROL, PRODUCTSYNONYM: VITAMIN D2 - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 20:06:57
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	13 Apr 2021 20:06:57
Data point term sent to Coder	System	13 Apr 2021 19:49:50
User closed query 'CDM-Coding: Please verify the spelling of the medication VITAMIN D12 (e.g VITAMIN D or VITAMIN B12 , etc). If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you. ' (Site from System).	System	13 Apr 2021 19:49:30
Query 'CDM-Coding: Please verify the spelling of the medication VITAMIN D12 (e.g VITAMIN D or VITAMIN B12 , etc). If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you.	Andrea Newlands (b) (4)	13 Apr 2021 19:49:30
' answered with 'updated' (Site from System).		
User entered 'VITAMIN D2' reason for change: Data Entry Error	Andrea Newlands (b) (4)	13 Apr 2021 19:49:16
User opened query 'CDM-Coding: Please verify the spelling of the medication VITAMIN D12 (e.g VITAMIN D or VITAMIN B12 , etc). If spelling is correct, please enter the active ingredients in parentheses following the drug name and make your change to the reported term. Thank you. ' (Site from System).	Coder Import (b) (4)	09 Apr 2021 06:04:44
Data point term sent to Coder	System	08 Apr 2021 15:10:27
User entered 'vitamin d12'	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'general health'	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '50000'	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'IU (IU)'	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'every week (QS)' reason for change:	Andrea Newlands (b) (4)	09 Apr 2021 16:22:44
Data Entry Error	(b) (4)	
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '07 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:09:33
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:09:33

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:09:33

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (35)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '803 (803)'	System	09 Apr 2021 16:22:44
User entered '804 (804)'	System	08 Apr 2021 15:09:33

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, PRODUCT: GABAPENTIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 15:21:41
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 Apr 2021 15:21:41
Data point term sent to Coder	System	08 Apr 2021 15:13:33
User entered 'gabapentin'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:13:22

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'motor vehicle accident'	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '100'	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'three times daily (TID)'	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '03 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:13:22
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Apr 2021 15:13:22

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:13:22

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (36)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 15:13:22

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: CARDIOVASCULAR SYSTEM, ATC: ANTIHYPERTENSIVES, ATC: ARTERIOLAR SMOOTH MUSCLE, AGENTS ACTING ON, ATC: HYDRAZINOPHTHALAZINE DERIVATIVES, PRODUCT: HYDRALAZINE HYDROCHLORIDE, PRODUCTSYNONYM: APRESOLINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 15:15:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:15:49
Data point term sent to Coder User entered 'apresoline'	System Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:14:41 08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'hypertension'	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '5'	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'three times daily (TID)'	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '01 Feb 2021'	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User entered '3'	System	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User entered '1'	System	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (37)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:20
User entered '804 (804)'	System	08 Apr 2021 15:14:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: THYROID THERAPY, ATC: THYROID PREPARATIONS, ATC: THYROID HORMONES, PRODUCT: LEVOTHYROXINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 15:16:47
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:16:47
Data point term sent to Coder	System	08 Apr 2021 15:15:43
User entered 'levothyroxine'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:15:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'hypothyroidism'	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '100'	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'ug (ug)'	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '03 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:15:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:15:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:15:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (38)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 15:15:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANESTHETICS, ATC: ANESTHETICS, LOCAL, ATC: AMIDES, PRODUCT: LIDOCAINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 15:46:29
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 Apr 2021 15:46:29
Data point term sent to Coder	System	08 Apr 2021 15:17:47
User entered 'lidocaine 4%'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'pain due to motor vehicle accident'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'I'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'application'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Topical (TOPICAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '14 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '09 Dec 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User entered '1'	System	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User entered '1'	System	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (39)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:27
User entered '804 (804)'	System	08 Apr 2021 15:17:29

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: MINERAL SUPPLEMENTS, ATC: OTHER MINERAL SUPPLEMENTS, ATC: MAGNESIUM, PRODUCT: MAGNESIUM OXIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 15:19:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:19:49
Data point term sent to Coder	System	08 Apr 2021 15:18:50
User entered 'magnesium oxide'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:18:00

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'general health'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '800'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'twice daily (BID)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:00
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '2'	System	08 Apr 2021 15:18:00

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:18:00

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (40)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 15:18:00

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: HYPNOTICS AND SEDATIVES, ATC: MELATONIN RECEPTOR AGONISTS, PRODUCT: MELATONIN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 15:19:48
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:19:48
Data point term sent to Coder	System	08 Apr 2021 15:18:50
User entered 'melatonin'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:18:35

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'general health'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '6'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:18:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:18:35

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered 'I'	System	08 Apr 2021 15:18:35

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (41)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 15:18:35

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: MUSCULO-SKELETAL SYSTEM, ATC: MUSCLE RELAXANTS, ATC: MUSCLE RELAXANTS, CENTRALLY ACTING AGENTS, ATC: CARBAMIC ACID ESTERS, PRODUCT: METHOCARBAMOL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 15:35:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:35:50
Data point term sent to Coder	System	08 Apr 2021 15:27:06
User entered 'methocarbamol'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:26:54

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'muscle spasms, motor vehicle accident'	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '750'	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'three times daily (TID)'	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '07 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:26:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '3'	System	08 Apr 2021 15:26:54

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:26:54

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (42)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 15:26:54

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
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: PANTOPRAZOLE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 15:34:43
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:34:43
Data point term sent to Coder	System	08 Apr 2021 15:34:17
User entered 'pantoprazole'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:33:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Gastroesophageal reflux disease'	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '40'	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '03 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:33:46
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:33:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:33:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (43)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 15:33:46

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: PSYCHOLEPTICS, ATC: ANXIOLYTICS, ATC: OTHER ANXIOLYTICS, PRODUCT: PAROXETINE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 15:35:52
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:35:52
Data point term sent to Coder	System	08 Apr 2021 15:35:18
User entered 'paroxetine'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'anxiety'	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '20'	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '01 Feb 2021'	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User entered '1'	System	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User entered '1'	System	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (44)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:39
User entered '804 (804)'	System	08 Apr 2021 15:34:26

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: VITAMINS, ATC: MULTIVITAMINS, PLAIN, ATC: MULTIVITAMINS, PLAIN, PRODUCT: VITAMINS NOS, PRODUCTSYNONYM: MULTIVITAMIN [VITAMINS NOS] - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	09 Apr 2021 05:35:25
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 05:35:25
Data point term sent to Coder	System	08 Apr 2021 15:39:26
User entered 'renal multivitamin'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:38:54

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'kidney general health'	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '1'	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'tablet (TABLET)'	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '03 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:38:54
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:38:54

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	08 Apr 2021 15:38:54

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (45)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	08 Apr 2021 15:38:54

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OTHER ANALGESICS AND ANTIPYRETICS, ATC: ANILIDES, PRODUCT: PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 15:49:49
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 15:49:49
Data point term sent to Coder	System	08 Apr 2021 15:48:44
User entered 'acetaminophen'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:47:50

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'pain, motor vehicle accident'	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '650'	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:47:50
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 15:47:50

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 15:47:50

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (46)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	08 Apr 2021 15:47:50

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: DRUGS FOR CONSTIPATION, ATC: DRUGS FOR CONSTIPATION, ATC: CONTACT LAXATIVES, PRODUCT: BISACODYL - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	08 Apr 2021 16:04:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 16:04:50
Data point term sent to Coder	System	08 Apr 2021 15:48:49
User entered 'bisacodyl'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'constipation prevention'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '10'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'suppository'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '01 Feb 2021'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User entered empty.	System	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User entered empty.	System	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (47)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:10:54
User entered empty.	System	08 Apr 2021 15:48:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: VARIOUS, ATC: GENERAL NUTRIENTS, ATC: OTHER NUTRIENTS, ATC: CARBOHYDRATES, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 21:06:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 21:06:45
Data point term sent to Coder	System	08 Apr 2021 15:58:18
User entered 'dextrose gel 40%'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'hypoglycemia'	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '15'	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'g (g)'	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '09 Dec 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User entered empty.	System	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User entered empty.	System	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (48)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:08
User entered empty.	System	08 Apr 2021 15:57:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 21:07:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	08 Apr 2021 21:07:47
Data point term sent to Coder	System	08 Apr 2021 15:59:18
User entered 'DEXTROSE SOLUTION 50%'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:12
reason for change: Data Entry Error	(b) (4)	
User entered 'dextrose solution'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'hypoglycemia'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '12.5'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'g (g)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '09 Dec 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User entered empty.	System	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User entered empty.	System	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (49)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:30
User entered empty.	System	08 Apr 2021 15:59:02

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: BLOOD AND BLOOD FORMING ORGANS, ATC: BLOOD SUBSTITUTES AND PERFUSION SOLUTIONS, ATC: I.V. SOLUTIONS, ATC: SOLUTIONS FOR PARENTERAL NUTRITION, PRODUCT: GLUCOSE, PRODUCTSYNONYM: DEXTROSE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 21:07:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 21:07:47
Data point term sent to Coder	System	08 Apr 2021 16:00:20
User entered 'dextrose solution 50%'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'hypoglycemia'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '25'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'g (g)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Intravenous (INTRAVENOUS)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '09 Dec 2020'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User entered empty.	System	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User entered empty.	System	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (50)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:38
User entered empty.	System	08 Apr 2021 15:59:53

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: SYSTEMIC HORMONAL PREPARATIONS, EXCL. SEX HORMONES AND INSULINS, ATC: PANCREATIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, ATC: GLYCOGENOLYTIC HORMONES, PRODUCT: GLUCAGON - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	08 Apr 2021 22:06:47
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	08 Apr 2021 22:06:47
Data point term sent to Coder	System	08 Apr 2021 16:01:21
User entered 'glucagon'	Andrea Newlands (b) (4) (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'hypoglycemia'	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'I'	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'mg (mg)'	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Intramuscular (INTRAMUSCULAR)'	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '09 Dec 2020'	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User entered empty.	System	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User entered empty.	System	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (51)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:45
User entered empty.	System	08 Apr 2021 16:00:55

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATIONS WITH ANTICHOLINERGICS INCL. TRIPLE COMBINATIONS WITH CORTICOSTEROIDS, PRODUCT: IPRATROPIUM;SALBUTAMOL, PRODUCTSYNONYM: ALBUTEROL;IPRATROPIUM - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 07:51:45
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:51:45
Data point term sent to Coder	System	09 Apr 2021 16:35:52
User entered 'ipratropium-albuterol'	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'cough'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '.5-2.5/3'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'mg/ml'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'intranasal'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '09 Dec 2020'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User entered empty.	System	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User entered empty.	System	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (52)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:53
User entered empty.	System	09 Apr 2021 16:35:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: ALIMENTARY TRACT AND METABOLISM, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: ANTIEMETICS AND ANTINAUSEANTS, ATC: SEROTONIN (5HT3) ANTAGONISTS, PRODUCT: ONDANSETRON HYDROCHLORIDE, PRODUCTSYNONYM: ONDANSETRON ODT - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 09:07:54
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 09:07:54
Data point term sent to Coder	System	09 Apr 2021 16:38:57
User entered 'odasetron odt'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'nausea'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '4'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'mg (mg)'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	(b) (4)	09 Apr 2021 16:38:17
	Andrea Newlands (b) (4)	
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '09 Dec 2020'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User entered empty.	System	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User entered empty.	System	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (53)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:11:59
User entered empty.	System	09 Apr 2021 16:38:17

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: NASAL PREPARATIONS, ATC: DECONGESTANTS AND OTHER NASAL PREPARATIONS FOR TOPICAL USE, ATC: OTHER NASAL PREPARATIONS, PRODUCT: SODIUM CHLORIDE - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 11:41:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 11:41:55
Data point term sent to Coder	System	09 Apr 2021 16:42:02
Data point term sent to Coder	System	09 Apr 2021 16:41:01
User entered 'SODIUM CHLORIDE'	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 16:40:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'HPONATREMIA'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0.65%'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '%'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User closed query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	(b) (4)	
	System	09 Apr 2021 16:41:29
User entered 'Other (OTHER)' reason for change: Data Entry Error	Andrea Newlands (b) (4)	09 Apr 2021 16:41:29
	(b) (4)	
User opened query 'Other, specify is provided, however Route of administration is not Other. Please correct.' (Site from System).	System	09 Apr 2021 16:40:42
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'intransal'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:40:42
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:40:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:40:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (54)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:40:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: HYDROCODONE BITARTRATE;PARACETAMOL, PRODUCTSYNONYM: HYDROCODONE/ACETAMINOPHEN - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 16:43:42
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	09 Apr 2021 16:43:42
Data point term sent to Coder	System	09 Apr 2021 16:43:05
User entered 'hydrocodone/acetaminophen'	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'pain, motor vehicle accident'	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '5/325'	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User closed query 'Future date has been entered. Please correct.' (Site from System).	System	09 Apr 2021 16:42:49
User entered '02 Nov 2020' reason for change: Data Entry Error	Andrea Newlands (b) (4)	09 Apr 2021 16:42:49
	(b) (4)	
User opened query 'Future date has been entered. Please correct.' (Site from System).	System	09 Apr 2021 16:42:35
User entered '02 Nov 2021'	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:42:35
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:42:35

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:42:35

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (55)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:42:35

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: NERVOUS SYSTEM, ATC: ANALGESICS, ATC: OPIOIDS, ATC: OPIOIDS IN COMBINATION WITH NON-OPIOID ANALGESICS, PRODUCT: OXYCODONE HYDROCHLORIDE;PARACETAMOL, PRODUCTSYNONYM: ACETAMINOPHEN W/OXYCODONE - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 09:11:06
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4)	12 Apr 2021 09:11:06
Data point term sent to Coder	System	09 Apr 2021 16:47:12
User entered 'oxycodone/acetaminophen'	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'pain, motor vehicle accident'	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '3/325'	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

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

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '02 Nov 2020'	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

Start date completely unknown

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:47:03
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:47:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:47:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (56)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:47:03

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

Name of Medication

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
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.	(b) (4) Coder Import (b) (4) (b) (4)	12 Apr 2021 07:08:55
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 07:08:55
Data point term sent to Coder	System	09 Apr 2021 16:49:17
User entered 'diclofenac 1%'	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'pain, motor vehicle accident'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'I'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Other (OTHER)'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'application'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'Topical (TOPICAL)'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '01 Oct 2020'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '0'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered '09 Dec 2020'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User entered empty.	System	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User entered empty.	System	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (57)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	02 May 2021 06:12:11
User entered empty.	System	09 Apr 2021 16:48:42

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
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.	(b) (4) Coder Import (b) (4)	09 Apr 2021 16:59:30
User coded data point as Term Coded data point by User: Coder System - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	09 Apr 2021 16:59:30
Data point term sent to Coder	System	09 Apr 2021 16:57:34
User entered 'tylenol'	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 16:56:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'pain, motor vehicle accident'	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '650'	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'mg (mg)'	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'as needed (PRN)'	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

If frequency is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Oral (ORAL)'	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '08 Sep 2020'	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:56:49
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:56:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:56:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (58)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered empty.	System	09 Apr 2021 16:56:49

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Name of Medication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
User coded data point as ATC: RESPIRATORY SYSTEM, ATC: DRUGS FOR OBSTRUCTIVE AIRWAY DISEASES, ATC: ADRENERGICS, INHALANTS, ATC: ADRENERGICS IN COMBINATION WITH CORTICOSTEROIDS OR OTHER DRUGS, EXCL. ANTICHOLINERGICS, PRODUCT: FLUTICASONE FUROATE;VILANTEROL TRIFENATATE, PRODUCTSYNONYM: BREO ELLIPTA - version WHODrug-Global-B3\\202003.	(b) (4) Coder Import (b) (4)	12 Apr 2021 06:59:50
User coded data point as Term Coded data point by User: (b) (6) - version WHODrug-Global-B3\\202003.	Coder Import (b) (4) (b) (4)	12 Apr 2021 06:59:50
Data point term sent to Coder	System	09 Apr 2021 16:58:35
User entered 'breo'	Andrea Newlands (b) (4) (b) (4)	09 Apr 2021 16:57:47

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Prophylaxis](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'cough'	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Dose per administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '1'	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Dose unit](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'puff (PUFF)'	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

If dose unit is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Frequency](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'once daily (QD)'	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[If frequency is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Route of administration](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Respiratory (Inhalation) (RESPIRATORY (INHALATION))'	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

If route of administration is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

Start date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '08 Sep 2020'	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Start date completely unknown](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered '0'	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Ongoing?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'Yes (Y)'	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

If not Ongoing, End date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Was this medication taken for solicited event?](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 13:30:21
	(b) (4)	
User entered 'No (N)'	Andrea Newlands (b) (4)	09 Apr 2021 16:57:47
	(b) (4)	

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Separate Dosage Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:57:47

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Unit Number \(derived\)](#)

Audit	User	Time (GMT)
User entered '1'	System	09 Apr 2021 16:57:47

US3412125

Folder: Concomitant Medication and Vaccination (1)

Form: Prior/Concomitant Medication and Vaccination (59)

Generated On: 09 Jun 2021 17:32:44

[Interval Dosage Definition \(derived\)](#)

Audit	User	Time (GMT)
User entered '804 (804)'	System	09 Apr 2021 16:57:47

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures Summary

Generated On: 09 Jun 2021 17:32:44

[Were any concomitant procedures performed?](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	03 May 2021 06:41:31
User signature succeeded.	Richard Powell (b) (4)	12 Apr 2021 14:34:56
User entered 'Yes (Y)' reason for change: Data Entry Error	(b) (4)	22 Oct 2020 14:32:00
User entered 'No (N)'	Mylene Asmar-Rios (b) (4)	11 Aug 2020 13:03:42
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered '18 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:35:40

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:32:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'TRACHESTOMY'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:35:40

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'Adverse Event (AE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:35:40

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (1)

Generated On: 09 Jun 2021 17:32:44

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:35:40

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered '18 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:15

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:32:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'BRONCHOSCOPY'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:15

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'Adverse Event (AE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:15

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (2)

Generated On: 09 Jun 2021 17:32:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:43
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:15

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:46
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered '18 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:54

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:32:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:46
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'PERCUTANEOUS ENDOSCOPIC GASTROSTOMY TUBE PLACEMENT'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:54

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:46
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'Adverse Event (AE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:54

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (3)

Generated On: 09 Jun 2021 17:32:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:46
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:36:54

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered '13 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:37:17

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:32:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'CLOSED RIGHT TIBIA-FIBULA FRACTURE'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:37:17

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'Adverse Event (AE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:37:17

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (4)

Generated On: 09 Jun 2021 17:32:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:50
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:37:17

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered '23 Sep 2020'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:42:06

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:32:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'BLOOD TRANSFUSION'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:42:06

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered 'Adverse Event (AE)'	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:42:06

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (5)

Generated On: 09 Jun 2021 17:32:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:48:53
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 22:05:11
User entered empty.	Mylene Asmar-Rios (b) (4)	22 Oct 2020 14:42:06

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:52
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User closed query 'Data entered is non-conformant. Please correct.' (Site from System).	(b) (4)	20 Apr 2021 18:41:41
User entered '18 Sep 2020' reason for change: Data Entry Error	System	20 Apr 2021 18:41:41
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	Steven Anderson (b) (4)	19 Feb 2021 19:21:23
User entered 'un Sep 2020' (non-conformant).	(b) (4)	19 Feb 2021 19:21:23

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:32:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:52
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered 'ventilatory support'	Andrea Newlands (b) (4)	19 Feb 2021 19:21:23

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:52
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered 'Adverse Event (AE)'	Andrea Newlands (b) (4)	19 Feb 2021 19:21:23

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (6)

Generated On: 09 Jun 2021 17:32:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:49:52
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered empty.	(b) (4)	19 Feb 2021 19:21:23
	Andrea Newlands (b) (4)	
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	KC Joubran (b) (4)	21 Apr 2021 13:53:04
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	19 Feb 2021 19:21:40
User entered 'un Sep 2020' (non-conformant).	Andrea Newlands (b) (4)	19 Feb 2021 19:21:40
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:32:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
User entered 'enteral nutrition'	Andrea Newlands (b) (4)	19 Feb 2021 19:21:40
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
User entered 'Adverse Event (AE)'	Andrea Newlands (b) (4)	19 Feb 2021 19:21:40
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (7)

Generated On: 09 Jun 2021 17:32:44

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	19 Feb 2021 19:21:40
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:50:02
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered '14 Sep 2020'	Andrea Newlands (b) (4)	06 Apr 2021 20:36:10

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:32:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:50:02
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered 'head ct'	Andrea Newlands (b) (4)	06 Apr 2021 20:36:10

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:50:02
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered 'Adverse Event (AE)'	Andrea Newlands (b) (4)	06 Apr 2021 20:36:10

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (8)

Generated On: 09 Jun 2021 17:32:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:50:02
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered empty.	(b) (4) Andrea Newlands (b) (4)	06 Apr 2021 20:36:10

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (*dd MMM yyyy*)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:50:05
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered '10 Sep 2020'	Andrea Newlands (b) (4)	06 Apr 2021 20:36:52

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:32:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:50:05
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered 'placement of extraventricular drains'	Andrea Newlands (b) (4)	06 Apr 2021 20:36:52

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:50:05
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered 'Adverse Event (AE)'	Andrea Newlands (b) (4)	06 Apr 2021 20:36:52

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (9)

Generated On: 09 Jun 2021 17:32:44

If indication is Other, specify

Audit	User	Time (GMT)
Data hard locked.	(b) (4), (b) (6)	01 May 2021 08:50:05
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered empty.	(b) (4) Andrea Newlands (b) (4)	06 Apr 2021 20:36:52

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	KC Joubran (b) (4)	21 Apr 2021 13:53:26
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Apr 2021 20:37:09
User entered 'un Sep 2020' (non-conformant).	Andrea Newlands (b) (4)	06 Apr 2021 20:37:09
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:32:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
User entered 'head MRI'	Andrea Newlands (b) (4)	06 Apr 2021 20:37:09
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
User entered 'Adverse Event (AE)'	Andrea Newlands (b) (4)	06 Apr 2021 20:37:09
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (10)

Generated On: 09 Jun 2021 17:32:44

[If indication is Other, specify](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	06 Apr 2021 20:37:09
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:32:44

Procedure/Surgery date (dd MMM yyyy)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
Query 'Data entered is non-conformant. Please correct.' canceled (Site from System).	KC Joubran (b) (4)	21 Apr 2021 13:53:39
	(b) (4)	
User opened query 'Data entered is non-conformant. Please correct.' (Site from System).	System	06 Apr 2021 20:37:25
User entered 'un Sep 2020' (non-conformant).	Andrea Newlands (b) (4)	06 Apr 2021 20:37:25
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:32:44

[Procedure/Surgery](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
User entered 'TTE'	Andrea Newlands (b) (4)	06 Apr 2021 20:37:25
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:32:44

[Indication](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
User entered 'Adverse Event (AE)'	Andrea Newlands (b) (4)	06 Apr 2021 20:37:25
	(b) (4)	

US3412125

Folder: Concomitant Procedures (1)

Form: Concomitant Procedures (11)

Generated On: 09 Jun 2021 17:32:44

If indication is Other, specify

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
	(b) (4)	
User entered empty.	Andrea Newlands (b) (4)	06 Apr 2021 20:37:25
	(b) (4)	

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
User entered '10/Sep/2020 12:59'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (1)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
User entered '1'		10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
User entered '22/Sep/2020 09:09'	System	22 Sep 2020 13:09:01

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (2)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		19 Oct 2020 14:06:06
User entered '1'		22 Sep 2020 13:09:01

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
User entered '19/Oct/2020 14:07'	System	19 Oct 2020 14:07:01

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (3)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		19 Oct 2020 14:08:03
User entered '1'		19 Oct 2020 14:07:01

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
User entered '20/Oct/2020 12:43'	System	20 Oct 2020 12:43:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (4)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
Reviewed for Safety.	(b) (4)	21 Oct 2020 13:54:54
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
User entered '1'		20 Oct 2020 12:43:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:54:29
User entered '21/Oct/2020 13:55'	System	21 Oct 2020 13:55:15

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (5)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:54:29
Reviewed for Safety.		22 Oct 2020 13:07:22
User entered '1'		21 Oct 2020 13:55:15

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	0 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	0 Oct 2020 12:43:14
Un-reviewed for Safety.		0 Oct 2020 12:43:11
Reviewed for Safety.		0 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	0 Oct 2020 17:24:19
Reviewed for Safety.		0 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:54:29
User entered '22/Oct/2020 13:07'	System	22 Oct 2020 13:07:45

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (6)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	10 Nov 2020 21:54:29
Reviewed for Safety.		23 Oct 2020 16:05:40
User entered '1'		22 Oct 2020 13:07:45

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	0 Oct 2020 17:24:19
Reviewed for Safety.		0 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	10 Nov 2020 21:54:29
User entered '23/Oct/2020 16:05'	System	23 Oct 2020 16:06:04

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (7)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
Reviewed for Safety.	(b) (4), (b) (6)	11 Nov 2020 17:50:24
DataPoint Verified.		10 Nov 2020 21:54:29
User entered '1'		23 Oct 2020 16:06:04

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:35:44
User entered '11/Nov/2020 17:50'	System	11 Nov 2020 17:50:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (8)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	19 Nov 2020 19:35:44
Reviewed for Safety.		19 Nov 2020 18:56:25
User entered 'I'		11 Nov 2020 17:50:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'		10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	19 Nov 2020 19:35:44
User entered '19/Nov/2020 13:56'	System	19 Nov 2020 18:56:47

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (9)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
Reviewed for Safety.	(b) (4), (b) (6)	25 Nov 2020 20:36:33
DataPoint Verified.		19 Nov 2020 19:35:44
User entered '1'		19 Nov 2020 18:56:47

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
User entered '25/Nov/2020 20:36'	System	25 Nov 2020 20:36:56

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (10)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		27 Nov 2020 18:01:31
User entered '1'		25 Nov 2020 20:36:56

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
User entered '27/Nov/2020 13:01'	System	27 Nov 2020 18:01:55

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (11)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		18 Dec 2020 18:24:24
User entered '1'		27 Nov 2020 18:01:55

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
User entered '18/Dec/2020 13:24'	System	18 Dec 2020 18:24:45

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (12)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		16 Feb 2021 20:38:53
User entered '1'		18 Dec 2020 18:24:45

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	0 Oct 2020 17:24:19
Reviewed for Safety.		0 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.		07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
User entered '16/Feb/2021 15:39'	System	16 Feb 2021 20:39:20

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (13)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		22 Feb 2021 15:35:58
User entered '1'		16 Feb 2021 20:39:20

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
User entered '22/Feb/2021 10:35'	System	22 Feb 2021 15:35:47

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (14)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		22 Feb 2021 15:35:58
User entered '1'		22 Feb 2021 15:35:47

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (15)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
User entered '07/Apr/2021 10:49'	System	07 Apr 2021 14:49:51

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (15)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 16:15:33
User entered '1'		07 Apr 2021 14:49:51

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (16)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
User entered '07/Apr/2021 12:15'	System	07 Apr 2021 16:16:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (16)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 14:43:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
User entered 'I'		07 Apr 2021 16:16:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (17)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
User entered '09/Apr/2021 13:39'	System	09 Apr 2021 20:40:20

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (17)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
Reviewed for Safety.	(b) (4), (b) (6)	20 Apr 2021 14:43:10
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
User entered 'I'		09 Apr 2021 20:40:20

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	
	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: Street

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: City](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (18)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered '20/Apr/2021 10:43'	(b) (4) System	20 Apr 2021 14:43:43

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (18)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	20 Apr 2021 14:43:43

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[SAEID](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	20 Oct 2020 12:43:14
Un-reviewed for Safety.		20 Oct 2020 12:43:11
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'USA-US061-2020-MRNA-1273-P301000005'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Serious

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Death](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Life threatening](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Requires inpatient or prolongation of existing Hospitalization](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'Yes (Y)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Persistent or significant disability or incapacity](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Congenital anomaly or birth defect](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Other medically important event](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		10 Sep 2020 16:59:10
User entered 'No (N)'	System	10 Sep 2020 16:58:33

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's First Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Richard'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gregory'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator's Last Name](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered 'Powell'	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: User entered 'Gottschlich'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Street](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '4260 Glendale Milford Road'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

Site Address: City

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered 'Cincinnati'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: State](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.		07 Apr 2021 14:49:11
User entered 'OH'	System	07 Apr 2021 14:45:50

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Site Address: Postal Code](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4), (b) (6)	14 Apr 2021 12:10:19
Reviewed for Safety.	(b) (4), (b) (6)	07 Apr 2021 14:49:11
Un-reviewed for Safety.	System	07 Apr 2021 14:45:50
DataPoint Un-verified.	System	07 Apr 2021 14:45:50
User entered empty.	System	07 Apr 2021 14:45:50
DataPoint Verified.	(b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.	(b) (4), (b) (6)	22 Sep 2020 13:08:52
Amendment Manager: User entered '45242'	System	14 Sep 2020 21:43:32

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[Investigator Country](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	16 Apr 2021 14:22:19
DataPoint Verified.	(b) (4) (b) (4), (b) (6)	20 Oct 2020 17:24:19
Reviewed for Safety.		22 Sep 2020 13:08:52
Amendment Manager: Data point set to conformant.	System	19 Sep 2020 03:37:15
User entered 'US' (non-conformant).	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form

Generated On: 09 Jun 2021 17:32:44

[E2B Transmit Flag \(Derived/Hidden\)](#)

Audit	User	Time (GMT)
User entered '19'	System	21 Apr 2021 13:07:07
User entered '18'	System	20 Apr 2021 14:43:43
User entered '17'	System	09 Apr 2021 20:40:20
User entered '16'	System	07 Apr 2021 16:16:16
User entered '15'	System	07 Apr 2021 14:49:51
User entered '14'	System	22 Feb 2021 15:35:47
User entered '13'	System	16 Feb 2021 20:39:20
User entered '12'	System	18 Dec 2020 18:24:45
User entered '11'	System	27 Nov 2020 18:01:55
User entered '10'	System	25 Nov 2020 20:36:56
User entered '9'	System	19 Nov 2020 18:56:47
User entered '8'	System	11 Nov 2020 17:50:50
User entered '7'	System	23 Oct 2020 16:06:04
User entered '6'	System	22 Oct 2020 13:07:45
User entered '5'	System	21 Oct 2020 13:55:15
User entered '4'	System	20 Oct 2020 12:43:33
User entered '3'	System	19 Oct 2020 14:07:01
User entered '2'	System	22 Sep 2020 13:09:01
User entered '1'	System	10 Sep 2020 16:59:16

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (19)

Generated On: 09 Jun 2021 17:32:44

[Date of submission \(Pre-filled from custom function\)](#)

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered '21/Apr/2021 06:06'	(b) (4) System	21 Apr 2021 13:07:07

US3412125

Folder: SAE USA-US061-2020-MRNA-1273-P301000005

Form: Safety Report Form (19)

Generated On: 09 Jun 2021 17:32:44

Check box to submit initial and significant follow-up concerning this SAE. By checking this box I hereby confirm all relevant data has been entered and reviewed to the best of my knowledge.

Audit	User	Time (GMT)
User signature succeeded.	Richard Powell (b) (4)	26 Apr 2021 14:40:17
User entered 'I'	(b) (4) (b) (4), (b) (6)	21 Apr 2021 13:07:07